

A RANDOMISED CONTROLLED TRIAL
INVESTIGATING THE INFLUENCES OF
FOOD FORM AND ENERGY DENSITY ON
APPETITE, SATIATION AND SATIETY IN
HEALTHY ADULTS

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Contents:

	Page
Relevant publications	II
Contents	III
List of tables	VII
List of figures	IX
List of abbreviations	XI
Declaration	XIII
Acknowledgements	XIV
Abstract	XV
Introduction	1
Chapter 1: Literature Review	5
1.1 An introduction to dysphagia	5
1.1.1 Epidemiology of dysphagia	6
1.1.2 Consequences of dysphagia	9
1.2 Management of malnutrition in hospitals	16
1.2.1 Food based oral nutrition support strategies	18
1.2.2 Improving energy intakes using oral nutritional supplements	29
1.3 Catering practices and food provision services	33
1.3.1 A history of the policies relating to hospital food provision in the UK	34
1.3.2 An overview of catering systems in place in hospitals	38
1.3.3 Challenges encountered with food provision services in hospitals	44
1.4 Nutritional management of dysphagia	50
1.4.1 Texture modified diets	51
1.4.2 TMDs for facilitating intakes	53
1.4.3 British National Guidelines for TMD	56
1.4.4 More food based strategies to improve intakes of those requiring a TMD	63
1.5 An overview of the regulation of food intake	66
1.5.1 GI hormones involved in the regulation of food intakes	75
1.6 External influences on eating behaviour: Focus of food form and energy density	82
1.6.1 Influence of food form on eating behaviour	83
1.6.2 Influence of energy density on eating behaviour	102
1.6.3 Influence of enrichment of TM meals on eating behaviour	114

	Page
1.7 Aims and objectives	115
Chapter 2: Development of study design, test meal and research protocol	118
2.1 Development of study design	118
2.1.1 Standard appetite methodology	121
2.1.1.1 Implications for main study	127
2.1.2 Experimental evidence	128
2.1.2.1 Implications for main study	134
2.1.3 Policies and guidelines	139
2.1.3.1 Implications for main study	142
2.1.4 Observation of institutional catering/food service provision	143
2.1.4.1 Implications for main study	146
2.2 Development of test meal	149
2.2.1 Texture development	157
2.2.2 Nutritional development	161
2.2.3 Cost estimations for test meal production	170
2.3 Development of research protocol: Feasibility study	172
2.3.1 Feasibility study: procedure	175
2.3.2 Feasibility study: outcomes and implications for main study	178
Chapter 3: Research methodology	180
3.1 Study pre-requisites	180
3.2 Study design	180
3.3 Subjects	181
3.3.1 Study sample	181
3.3.2 Power calculation	182
3.3.3 Recruitment strategy	184
3.4 Experimental procedure	192
3.4.1 Initial consultation and screening	192
3.4.2 Testing session procedure	196
3.5 Outcome measures	201
3.5.1 Ad libitum food and energy intake at the test meal	201
3.5.2 Daily energy intakes	202
3.5.3 Post-meal intakes	204

	Page
3.5.4 Appetite sensations and palatability assessed using VAS	206
3.5.5 Period of time taken to consume meal to point of satiation	207
3.5.6 Period of satiety	207
3.5.7 Energy compensation	207
3.6 Data analysis	210
3.6.1 Food intakes	211
3.6.2 Daily energy and macronutrient intakes	212
3.6.3 Appetite and palatability ratings	212
3.6.4 Period of satiety	213
3.6.5 Time to consume meal until point of satiation	214
Chapter 4: Results	215
4.1 Subjects	215
4.1.1 Subject characteristics	215
4.2 Food (g) and fluid (ml) intakes	216
4.2.1 Test meal food intakes	216
4.2.2 Test meal fluid intakes	217
4.3 Energy and nutrient intakes	218
4.3.1 Breakfast energy and macronutrient intakes	218
4.3.2 Breakfast micronutrient intakes	219
4.3.3 Test meal provisions	220
4.3.4 Test meal energy intakes	221
4.3.5 Test meal macronutrients intakes	222
4.3.6 Test meal micronutrient intakes	222
4.3.7 Post-meal energy and macronutrient intakes	224
4.3.8 Post-meal micronutrient intakes	225
4.3.9 Daily energy intakes	225
4.3.10 Correlations between test meal energy intake and daily energy intake	226
4.3.11 Daily micronutrient intake	228
4.3.12 Daily micronutrient intake	229
4.4 Energy compensation	230
4.5 Appetite parameter results	231
4.5.1 Baseline appetite ratings	231
4.5.2 Appetite ratings over time	232

	Page
4.5.3 Between meal comparisons	234
4.6 Palatability rating results	236
4.6.1 Association between food intakes and appetite and palatability ratings	236
4.7 Time until satiation and period of satiety	238
4.7.1 Time until satiation	238
4.7.2 Period of satiety	239
Chapter 5: Discussion	240
5.1 Discussion	240
5.2 Application and considerations	273
5.3 Future work	298
Chapter 6: Conclusion	302
References	306
Appendices	331

List of tables:

Chapter 1	Page
1.1 The impact of dysphagia on the swallowing process at each stage and possible dietary prescription for management	8
1.2 Common causes of malnutrition and whether cause can be implicated in dysphagia	14
1.3 Commonly reported effects and consequences of malnutrition	15
1.4 Systematic approach to evaluation and treatment of malnourished patients	16
1.5 Summary of the benefits of food based strategies	28
1.6 Advisory Committee Borderline Substances (ACBS) indications for ONS	30
1.7 History of institutional food policies and guidelines	36
1.8 Overview of patient satisfaction of hospital food provision services	45
1.9 Challenges for food provision for those prescribed a TMD	62
1.10 Summary of the studies investigating food form on appetite and food intakes	98
1.11 Summary of the studies investigating the effect of energy density on appetite and food intakes	111
 Chapter 2	
2.1 Overview of confounder encountered in appetite research and their potential impact on appetite study designs	129
2.2 Descriptors for a Texture C “thick puree diet”	140
2.3 Energy and protein guidelines per standard and energy dense meal	141
2.4 Issues encountered and solution/ modifications made during trial of initial recipe for test meal	153
2.5 Standard protocol for texture modification of test meals	159
2.6 Total nutrient composition of test meals	162
2.7 Individual test meal components energy and protein content	165
2.8 Nutrient composition of the test meal compared to alternatives	167
2.9 Estimated moisture losses experienced with cooking	168
2.10 Expected moisture losses experienced with cooking	169
2.11 Overview of estimated cost of ingredients for each test meal	171
2.12 Cost of producing test meal as % of daily expenditure per person compared with “ready meal” versions	172
2.13 Overview of uncertainties of proposed research protocol	174

	Page
2.14 Observations from feasibility study and implications for main study	179
 Chapter 3	
3.1 Power and sample size calculation from similar studies	183
3.2 Qualitative feedback: reasons from poor response rate in older adults	189
 Chapter 4	
4.1 Subject characteristics	216
4.2 Mean (SD) food (g) and energy (kcal) intakes	217
4.3 Mean (SD) breakfast micronutrient intakes	220
4.4 Mean (SD) intakes consumed and provided at test meal	223
4.5 Mean (SD) post-test meal macronutrient intakes	225
4.6 Mean (SD) post-test meal micronutrient intakes	226
4.7 Relationship between test meal energy intake and daily energy intake	227
4.8 Mean (SD) daily macronutrient intakes	228
4.9 Mean (SD) daily micronutrient intakes	230
4.10 Percentage energy compensation with energy density	231
4.11 Correlation coefficients for appetite ratings and food intake	238
 Chapter 5	
5.1 The effect of enriching meals to varying levels on potential intakes	244
5.2 Those identified as not being suitable for consuming the test meal	281
5.3 Cost comparisons between food ingredients and proprietary products used for enrichment	289

List of figures:

	Page
Chapter 1:	
1.1 Overview of meal provision services in hospitals	41
1.2 Overview of the interaction of the mechanisms involved in the regulation of appetite and food intake	68
Chapter 2:	
2.1 Overview of the synthesis of literature and policies to develop the research study design and methodology	121
2.2 An overview of the test meals necessary to fulfil research aims	139
2.3 An overview of practice, policy and evidence/literature to develop research study design and methods	148
2.4 Standard texture meal layers	160
2.5 Blending meat component of test meal	160
2.6 Each meal component demonstrating that it holds own shape as required	160
2.7 Texture modified test meal	160
Chapter 3	
3.1 Overview of recruitment process	191
3.2 Format of consultation sessions	192
3.3 Outline of test day for participants	200
Chapter 4:	
4.1 Overview of participants through trial	215
4.2 Mean (standard error) fluid intakes at test meal	218
4.3 Mean (SEM) energy intake at breakfast	219
4.4 Relationships between test meal energy intake and daily energy	227
4.5 Mean (SEM) fat intake at each meal occasion across test days	229
4.6a Appetite-time profiles for ratings of hunger	232
4.6b Appetite-time profiles for ratings of fullness	233
4.6c Appetite-time profiles for ratings for desire to eat	233

4.7a Mean AUC for hunger	234
4.7b Mean AUC for fullness	235
4.7c Mean AUC for desire to eat	236
4.8 Appetite time profile for ratings of palatability	236
4.9 Mean AUC for palatability	237
4.10 Time until next eating occasion for each meal condition	239

List of abbreviations

AA: Amino acids
ABV: Alcohol by volume
ACBS: Advisory Committee on Borderline Substances
AgRP: Agouti related peptide
AUC: Area under curve
BAPEN: British Association of Parenteral and Enteral Nutrition
BDA: British Dietetic Association
BMR: Basal metabolic rate
CART: Cocaine- and amphetamine-regulated transcript
CCK: Cholecystokinin
CINAHL: Cumulative Index to Nursing and Allied Health Literature
CONSORT: Consolidated Standards of Reporting Trials
CFU: Customary food unit
CHO: Carbohydrate
CNS: Central nervous system
CP: Cerebral palsy
cP: Centipoise
CVA: Cerebrovascular accident
DF: Dietary fibre
DIT: Dietary induced thermogenesis
EE: Energy expenditure
EPI: Echo-planar magnetic resonance imagery
FAs: Fatty acids
fMRI: Functional magnetic resonance imagery
FRC: Food record chart
GERD: Gastroesophageal reflux disease
GI: Gastrointestinal
GIP: Gastric inhibitory polypeptide
GLP-1: Glucagon like peptide 1
HCA: Hospital Caterers Association
HED: High energy dense
IBD: Inflammatory bowel disease
ISD: Information services division
kcal: Kilocalorie
kg: Kilogram
kJ: Kilojoule
LED: Low energy dense
MESH: Medical subject headings
MND: Motor neuron disease
MRI: Magnetic resonance imagery
MS: Multiple sclerosis
NHR: Nursing home residents
NHS: National Health Service
NPY: Neuropeptide Y
NSP: Non starch polysaccharide
NST: Nucleus of the tractus solarius
NSW: Nutrition screening week
ONS: Oral nutritional supplements

OPT: Oral processing time
Pa.s: Pascal-second
PET: Positron emission tomography
PMI: Protected mealtimes initiative
PNS: Peripheral nervous system
PYY: Peptide YY
QIS: Quality Improvement Scotland
QOL: Quality of life
QMU: Queen Margaret University
RCSLT: Royal college of Speech and Language therapists
RM ANOVA: Repeated Measures Analysis of variance
SFU: Small food unit
SLT: Speech and language therapist
SIGN: Scottish Intercollegiate Guidelines Network
SOP: Standard operating procedure
SSS: Sensory specific satiety
ST ED: Standard texture energy dense
ST SE: Standard texture standard energy
TMD: Texture modified diet
TM ED: Texture modified energy dense
TM SE: Texture modified standard energy
UK: United Kingdom
VAS: Visual analogue scale
WHO: World Health Organisation

Declaration:

I declare that the work contained within this thesis is original. I have solely been responsible for the organisation and day to day running of the study contained herein, as well as all of the aspects of data collection and the analysis of the results, unless otherwise referenced.



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Abstract:

Background: Texture and energy density are two physical properties of foods known to impact on eating behaviour. For those with mastication and/or deglutition disorders; diets which have their texture altered are prescribed. Further these texture modified diets may be energy enriched in an effort to optimise the opportunity for individuals prescribed them to meet their required energy intakes. However there is insufficient evidence supporting this strategy. No well controlled studies have been conducted evaluating these alterations (made in line with clinical guidelines), which specifically investigates their impact on eating behaviour. As such despite their intention to facilitate food and energy intakes it is unknown if these diets are in fact fit for purpose.

Objective: To investigate the effect of texture modification, and/or energy enrichment of a standard meal developed to meet current recommendations for meal provision in hospitals on appetite parameters and food and energy intakes at a single eating occasion, in healthy adults.

Design: A single blind, randomised crossover within-subjects design, where on four occasions 33 healthy adults consumed a test meal at lunch until satiation (*i.e.* meal termination) was reached whilst rating their appetite parameters. The meal had its texture and/or energy density altered to compare the effects of food form and energy density on appetite and satiation. The quantity of meal consumed was calculated using a plate wastage method. Subsequent intakes were recorded in a food diary to determine the effect of the treatments on satiety and identify any evidence of energy compensation. Food (g) and energy intakes (kcal) consumed during the feeding session were analysed using repeated measures ANOVA.

Results: Test meal energy intakes (kcal) were significantly higher with energy enrichment of both meals (standard texture (ST); 315 kcal and texture modified (TM); 303 kcal ($p=0.001$)). Area under the curve (AUC) did not differ between meals for hunger, fullness, or desire to eat however palatability was significantly reduced with texture modification. Regardless of the composition and quantity consumed at the test meal, post-meal energy and macronutrient intakes remained the same across all days. Evidence of partial energy compensation was revealed (15 % (ST) and 22% (TM)) thus energy intakes remained higher over the day for both (260 kcal and 225 kcal respectively) ($p<0.05$).

Conclusions: Enriching a meal, suitable for provision in a hospital setting results in significantly greater energy content without impacting on rated palatability. In a well-controlled, healthy sample, this enriched meal was sufficient to increase energy intakes (kcal) at an individual eating occasion for both ST and TM meals without affecting absolute food intake (g) or appetite responses (between meals) at the testing session. Incomplete subsequent energy compensation resulted in daily energy intakes remaining significantly higher with consumption of the enriched meals. Thus energy enrichment at a single meal, appropriate for provision for patients requiring a “Texture C” diet appears to be a suitable method to optimise short term energy intakes, in a healthy sample not confounded by disease state. Further investigation into enrichment of these meals in a clinical setting is justified.

Keywords: Appetite, satiation, satiety, texture (modified diet), energy density (enrichment).

Introduction:

Strategies which focus on manipulating the properties of foods to impact on eating behaviour have been extensively researched in relation to weight management. However in the main, the primary aim of these studies has been to reduce energy intakes and therefore promote weight loss. This particular research study is however interested in the use of food based strategies for increasing energy intakes to prevent weight loss, thereby maintaining or improving weight status. These strategies may benefit individuals who are malnourished or at risk of becoming malnourished (currently estimated at 3 million adults in the UK (BAPEN 2012a)).

The term malnutrition can refer to a deficiency, excess or imbalance of a wide range of nutrients, resulting in adverse effects on body composition, function and clinical outcome (Saunders et al. 2010). It should be clarified that in the context of this research, the term malnourishment refers to a state of under nutrition as a result of insufficient energy intake. Individuals at particular risk of becoming malnourished are those who struggle with mastication and/or deglutition (dysphagia), who when feeding via the oral route is possible, are prescribed a texture modified diet (TMD). It should be acknowledged that whilst TMD are a cornerstone in the nutritional management of dysphagia, they may also be prescribed for those with general mastication difficulties, or compromised dental status.

To promote intakes and prevent malnutrition associated with prescription of these diets, it is advocated that these texture modified meals be enriched to increase the energy density of the meals (Thomas 2001; SIGN 119 2010). This strategy may also

be adopted for those without mastication and deglutition difficulties but who have reduced appetites and hence struggle to consume adequate food volumes (Gall et al. 1998; Odlund Olin et al. 1996; 2003). Despite the recommendation of enrichment for improving energy intakes, no randomised controlled studies, conducted in a healthy sample exist, which specifically assess its impact on eating behaviour. In fact, there remains a general lack of studies assessing food based strategies for the management of malnutrition and dysphagia.

Whilst this research study alone cannot address all of the uncertainties surrounding nutritional management strategies, it aims to investigate one key aspect; energy enrichment of meals, including texture modified meals that are offered in clinical, care home and community settings. For the context of this research, the term ‘enrichment’ refers to the addition of energy (kcal) to foods resulting in foods with greater energy density.

For this strategy to be successful, consideration to the alterations and their influence on appetite and eating behaviour must be addressed. Studies investigating eating behaviour can be confounded by a range of factors and it is true that investigating appetite in a hospital population may indeed further complicate the interpretation of the results. Therefore, well controlled studies using healthy individuals, are required initially in order to determine the potential of these strategies, whilst considering how they may apply in a clinical context. Following these, further investigation into their success when applied in a clinical setting is warranted.

Literature search:

The literature was searched using the databases Medline, Science Direct, Cochrane, and CINAHL. The chosen keywords were based on MESH-terms from the PubMed database, and when searching in other databases it was attempted to use those terms as well. Planned search strategies, considering suitable Boolean operators were used in order to draw literature from the clinical settings as well as experimental appetite studies. Strategy one: 1) dysphagia OR deglutition disorders, 2) malnutrition OR aspiration OR quality of life, 3) texture OR food OR enrichment OR energy intake, 4) treatment OR nutrition, 5) humans, 6) NOT children. Strategy two: 1) texture OR food form OR viscosity, 2) enrichment OR energy density, 3) appetite OR energy intakes, 4) humans, 5) NOT children. Strategy three: 1) eating behaviour OR appetite 2) CCK OR GLP-1 OR PYY, OR hormones AND 3) elderly OR ageing AND 4) ill OR disease OR critical OR hospitalised. Searches were confined to the English language and initially from publication dates between 2000 and 2013. Search restrictions by publication dates were applied in order to ensure the evidence was relevant, and reflective of the ongoing developments in both appetite research and the literature aligned with guidance relating to hospital food provision.

Where possible, studies with the highest level of evidence were included. However as aspects of this area (particularly nutritional management strategies via food based methods) are sparsely examined, studies with lower levels (e.g. cohort studies) of evidence were included also. Government documents were also consulted including current policies and guidelines surrounding hospital food provision, as well as reports and key findings from audits. Unfortunately few recent (post 2010) audits were identified; thus some findings fail to represent recent changes in food provision.

Where findings from these older audits have been included, their potential lack of reliability and relevance has been highlighted.

This systematic approach revealed that there was a general lack of food based experimental studies assessing strategies to increase energy intakes. Instead a number of poorly controlled studies, reviews and opinion pieces with limited evidence of a scientific basis were found. It was highlighted almost five years ago that there are a general lack of food based studies assessing strategies to manage malnutrition (Weekes et al. 2009). However there continues to be a lack of well controlled food based studies to contribute to the literature, surrounding nutritional management of malnutrition. Further, few studies have specifically investigated the effectiveness of food based strategies for managing malnutrition in those requiring TMDs. Of these, only three studies (two RCTs and one cohort study) assessed increases in energy intakes (from food) as an outcome measure. Ample studies investigating the influence of food properties such as texture and energy density were identified. However these have been conducted with the aim of reducing energy intakes, and even still reveal conflicts in the literature.

The following literature review aims to appraise the currently available evidence surrounding nutritional management strategies which specifically include both texture modification and alterations in energy density. The influence of these alterations on eating behaviour is central to the success of these strategies for managing nutritional intakes. Therefore both texture and energy density and their effect on eating behaviour were reviewed whilst addressing current practices in the clinical setting, including the enrichment of standard meals and texture modified meals for those with dysphagia.

Chapter 1:

Literature review

1.1 An introduction to dysphagia:

Dysphagia refers to a disruption in the swallowing process by preventing the optimal transfer of bolus from the mouth to the stomach (Payne et al. 2011). Therefore signs and symptoms of dysphagia may be related to anatomical or physiological disorders occurring in the mouth, pharynx, larynx or oesophagus (Crary and Groher 2003). For the context of this thesis, the term dysphagia relates to those who encounter difficulty with any aspect of food consumption via the oral route (*i.e.* bolus manipulation during the preparatory stage, mastication during the oral phase, as well as the swallow initiation during the pharyngeal stage (Table 1.1)).

Normal swallowing (deglutition) is a complex coordinated process with two essential functions; bolus transport and airway protection (Forster et al. 2011). Both of these functions can be compromised with dysphagia (section 1.1.2). Deglutition occurs in four main stages; preparatory, oral, oesophageal and pharyngeal. Detailed description of the normal physiology of deglutition can be found elsewhere (Shaw and Martino 2013) however it has been summarised (Table 1.1) to include how these stages can be affected by dysphagia. It should be highlighted that the specificity of the stages of a normal swallow are variable depending on factors such as bolus consistency and volume, and also the age of the individual (Daniels and Huckabee 2008). For example, increased oral transit time has been observed in healthy older individuals (Cook et al. 1994; Shaw et al. 1995), and also with increased viscosity of the bolus

(Dantas et al. 1990), whereas decreased oral transit time was observed with increased bolus volume (Rademaker et al. 1998) in healthy women. These factors, leading to variability between individuals add to the complexity of optimal nutritional management of those experiencing mastication and swallowing impairments (section 1.4).

1.1.1 Epidemiology of dysphagia:

Dysphagia results from various medical conditions such as; stroke, head/neck or oesophageal cancer, neurodegenerative diseases (for example; motor neuron disease (MND), multiple sclerosis (MS), Parkinson's disease, and Alzheimer's disease) neurological trauma, and dementia (Rofes et al. 2011). The prevalence of dysphagia is therefore generally higher in institutionalised settings such that prevalence can reach over 50% in hospitalised patients with acute illnesses or in nursing home residents aged 65 years or older (Forster et al. 2011). Dysphagia is associated with a range of conditions, therefore although it is particularly prevalent in an older population; it can be observed across the lifespan. For example, dysphagia accompanies conditions such as cerebral palsy (CP) which in the UK affects about one in every 400 children (2 out of 1000 live births in the UK (Odding et al. 2006; NICE 2010).

Dysphagia is however most commonly associated with cerebrovascular disease with reported prevalence of dysphagia after stroke ranging from 37% to 78% (Martino et al. 2005). The actual incidence may even be higher as dysphagia is often under reported because a number of patients fail to recognise and report the problem. It has

in fact been shown that patients underestimate the severity of the condition when compared with objective measures (barium swallow examination) (Elmståhl et al. 1999).

Epidemiological data on dysphagia in the general population are scarce, with most studies being limited to older adults, or hospitalised individuals. Eslick and Talley (2008) however carried out a community based epidemiological study in Australia including 926 subjects of whom 16% (110 subjects) reported to ever have experienced dysphagia. The reported prevalence of dysphagia peaked in those aged 40-49 years which is arguably younger than would often be expected since the prevalence of the conditions that most commonly predispose dysphagia increase with advancing age. It is not known what specifically caused the high prevalence of reported dysphagia in this group, however it demonstrates that the reported prevalence of dysphagia, even in the community, can be high and may be linked to a greater range of conditions than previously thought (for example; high blood pressure (OR = 2.58, 95% CI: 1.22–5.44) and gastroesophageal reflux disease (GERD) (OR = 2.96, 95% CI: 1.76–4.98)).

This supports the need for community accessible nutritional management strategies, particularly in those who can tolerate oral feeding who are more likely to be able to self-manage their condition using compensatory techniques, such as the consumption of texture modified diets (TMD) (Table 1.1, discussed in detail in section 1.4.1). In These diets, which include thickened fluids and foods with modified textures are advocated on the basis that they will facilitate mastication, allowing greater control of the bolus in the oral cavity. In theory, such diets also slow transit of the ingested material allowing greater control and time for the airway to protect itself against

invasion from the bolus. Whilst two studies (Logemann et al. 2008; Diniz et al 2009 (discussed subsequently, section 1.4.2) have demonstrated reduced aspiration with increased fluid viscosity, there is insufficient evidence demonstrating that TMD are universally effective for preventing aspiration. Nicosia and Robbins (2001) demonstrated that in general as viscosity increases, bolus ejection time increases arguably allowing greater time for airway protection. However it is likely that this is due to a complex interaction among variations in bolus material properties (for example viscosity, volume and density), applied lingual pressure, and the resulting fluid motions. This suggests that the mechanical effect of thickened liquids (within a TMD) may be non-uniform among dysphagic individuals.

Table 1.1: The impact of dysphagia on the swallowing process and possible dietary prescriptions for its management

Stages of normal swallow	Affected by ¹	Consequences ¹	Possible resulting dietary prescription²
Preparatory	Reduced movement of facial muscles, lips, tongue and jaw Loss of sight, smell and/or taste	Difficulty getting food into mouth, difficulty in sealing the mouth Reduced saliva production	Fork mashable, pre-minced, thick puree, thin puree
Oral	Reduced range of movement of facial muscles, lips, tongue and jaw Lack of saliva	Difficulty in mastication, difficulty forming a food bolus, difficulty in controlling a food bolus	Pre minced, thick puree, thin puree
Pharyngeal	Absence of swallow reflex	Inability to swallow safely	Thick puree
Oesophageal	Impaired peristalsis or obstruction	Food fails to move into the stomach Aspiration after the swallow	Thick puree

¹ Thomas, 2001, ² BDA, 2012 (a)

² Fork mashable; Texture “E”, Pre minced; Texture “D”, Thick puree; Texture “C”, Thin puree; Texture “B”.

TMD are a widely prescribed therapeutic diet, however despite their worldwide prescription the literature investigating the potential of these diets for improving health outcomes is limited. Additional issues exist with these diets including; a general inconsistency in the terms used to describe them (Penman and Thompson 1998; Cichero et al. 2013) and their unstandardised preparation methods (Steele et al. 2003; Rosenvinge and Stark 2005). A full description of the nutritional management of dysphagia, including issues and controversies associated with TMD is discussed later (section 1.4).

1.1.2 Consequences of dysphagia

If not managed effectively the consequences of dysphagia can range from increasing morbidity to impacting on mortality in some cases. As well as increasing hospital stay (Broadley et al. 2003), dysphagia is a major factor in aspiration (DeLegge 2002), reduced quality of life (QOL) (Ekberg 2002), and reduced food and fluid intakes (Wright et al. 2005; Bannerman and McDermott 2009) which can contribute to malnutrition and dehydration.

Aspiration is the entry of liquid or particulate matter into the tracheobronchial tree, as a consequence of passive regurgitation or active vomiting of gastric contents from patients without sufficient laryngeal protection reflexes (Janda et al. 2006) and often occurs in patients with swallowing impairment or abnormality (DeLegge 2002). The aspiration of ingested bolus may introduce oral bacteria to the lungs which can cause aspiration pneumonia. This can be serious and accounts for 13% to 48% of all infections in nursing home residents (DeLegge 2002). Clinically, aspiration

pneumonia is evidenced by coughs indicating material is penetrating the airway (SIGN 119 2010) as well as typical symptoms of pneumonia, such as fever or shaking chills (Janda et al. 2006).

Silent aspiration can also occur; in fact it was found that 68% of stroke patients that were observed to aspirate on video fluoroscopy failed to cough (Perry and Love 2001). Although the provision of a texture modified diet (TMD) (discussed in detail section 1.4), including thickened fluids is advised to avoid aspiration (Nicosia and Robbins 2001), this may still occur (Logemann et al. 2008; Diniz et al. 2009). However, other nutritional management methods which bypass the oral phase may also result in complications. For example, Finucane et al. (1999) did not find evidence that non-oral feeding (*i.e.* enteral tube feeding) prevented aspiration pneumonia in dementia patients.

It has also been demonstrated that individuals with dysphagia have reduced QOL (Ekberg et al. 2002). Dysphagia can adversely affect social and mental health and lead to considerable isolation and meal related anxiety (Patterson 1996). The condition destroys the social opportunities and pleasures of mealtimes, affecting the patient's relationships with care givers and family, and can also undermine health and confidence (Ekberg et al. 2002). For example; patients can find the coughing, spluttering and loss of food from the mouth that they can experience with dysphagia very upsetting and degrading which impacts on QOL (Kemp 2001). Thus the importance of providing diets of appropriate consistencies which enable safe swallow is reinforced. Aside from the fact that eating is often regarded to be a pleasurable experience, which can have positive psychological effects, good nutrition

improves QOL by promoting health and preventing dietary deficiency disease (Amarantos et al. 2001).

The social aspects of eating are also well documented such that QOL can improve by adding a social element to meal times. For healthy individuals meals are often the focus of celebrations and therefore are considered social and pleasurable experiences (Ekberg et al. 2002). In institutionalised individuals mealtimes can give structure to the day, especially for those who may be bed bound or do not have any activities within the day. To ensure holistic health is achieved, as well as the promotion of energy intakes it is important that mealtimes remain pleasurable experiences.

It has however been observed that individual's receiving a TMD have lower food intakes compared to those receiving a normal texture diet (Johnson et al. 1995; Nowsen et al. 2003; Wright et al. 2005; Bannerman and McDermott 2011). Those requiring TMDs may have reduced appetites associated with disease (Muscaritoli et al. 2010) or aging (Morley 2001). Thus it is unclear if these reduced intakes are due to the dietary prescription, a disruption in the regulation of food intake, or a combination of these.

It is recognised that those prescribed a TMD tend to consume a limited variety of foods which may contribute to their overall reduced intakes. This may be due to the fact that only certain foods can be modified to meet the required texture, and also because individuals may tend to stick to foods which they know they can tolerate. For example, those with mastication issues may be inclined to consume foods that are soft and therefore require minimal chewing. This restriction in dietary intake could result in the elimination of hard fruits and vegetables such as raw apples and

carrots, and meats that require significant chewing such as certain cuts of beef for example; brisket or stewing steak. Similarly, swallowing difficulties may also cause self-restriction of the diet, especially avoiding dry and sticky foods such as bread and rice which may not be easily tolerated as a result of the swallowing disorder (BDA 2012a). As a consequence a diet of limited variety ensues which may further lead to nutrient deficiencies.

Wright et al. (2005) compared 24 hour dietary intakes of older people consuming a TMD (n=30) with older people consuming a normal texture hospital diet (n=25) using weighed food intakes and food record charts. It was found that daily energy intakes were significantly lower (535 kcal/ 2239 kJ, $p<0.0001$) in the TMD group (923 kcal/ 3877 kJ) than the normal texture group (1456 kcal/6115 kJ). Interestingly, authors also reported that the energy intakes within the TMD of different categories (normal (n= 25), Texture E, “soft, moist foods” (n= 11), Texture D, “moist and requires little chewing” (n= 9) and Texture B, “thick custard consistency” (n= 10)) reduced as the diet had its texture modified to a greater degree. Daily energy intakes were reported as 1456 kcal /6115 kJ (normal diet), 1200 kcal/ 5040 kJ (Texture E), 769 kcal/ 3230 kJ (Texture D), and 734 kcal/ 3083 kJ (Texture B).

Bannerman and McDermott (2011) also demonstrated lower daily energy intakes (measured over three days) in those consuming a TMD (n=15) relative to a group with similar characteristics receiving a standard texture diet (n=15) in three residential care homes in the UK. Those receiving a TMD had significantly lower daily energy intakes (1312 ± 326 kcal versus 1569 ± 260 kcal). This represented a 257 kcal difference in daily energy intakes between the two groups, which if maintained is likely to influence nutritional status over time. Authors in these

aforementioned studies did not report energy consumption compared to provision therefore whether these reduced intakes are due to the therapeutic dietary prescription (including aesthetics and nutritional content) or solely to the disease state which accompanies the dysphagia, remains unclear.

Studies however reported reduced nutritional quality with additional degrees of modification (Vigano et al. 2011). For example, it was reported that compared to normal diets; pureed and liquid diets presented higher moisture content as well as reduced energy (31.4 % and 39.9 % respectively), protein (45.4 % and 79.8% respectively) and lipid (31.4 % and 39.9 % respectively) content. This suggests that it is important to ensure that these diets are sufficient to meet requirements, and may therefore need to be enriched during texture modification. Enrichment of these diets may help to compensate for the reduced energy density of the meals, and also for the potentially reduced food intakes. However this is yet to be assessed, in a controlled experimental setting.

Not only are lower food intakes an observed issue with TMD, but adequate fluid intakes are also a concern. For example, Bannerman and McDermott (2011) demonstrated that those receiving a TMD compared to a standard texture diet consumed significantly less fluids (1196 ± 288 ml versus 1611 ± 362 ml, $p < 0.02$) such that those receiving a TMD did not meet their recommended fluid intakes. These studies certainly highlight the difficulty in achieving required nutritional and fluid intakes with the prescription of a texture modified diet. Thus further strengthening the argument for the need for additional work in the development of these meals to maximise the opportunity for these vulnerable individuals to achieve

adequate intakes. Reduced fluid and food intakes are in fact a chief aetiological cause in disease related malnutrition (Table 1.2).

Table 1.2: Common causes of malnutrition and whether cause can be implicated in dysphagia

Cause	Risk factors	Implicated in dysphagia
Decreased dietary intake ^{1,4}	<ul style="list-style-type: none"> ○ Reduced appetite due to illness ⁷ ○ Reduced appetite due to anorexia of aging ⁸ ○ Reduced appetite due to medications ³ ○ Inadequate or unappetising meals ○ Difficulty self-feeding ¹ ○ Mastication and swallowing disorders ^{1,3} ○ Psychological factors: depression, isolation, loneliness ^{1, 5} ○ Food insecurity ¹ 	Possibly * Possibly * Possibly * Yes ⁶ Yes ⁵ Yes Yes ⁵ Not specifically
Increased nutritional requirements ⁴	<ul style="list-style-type: none"> ○ Increased BMR during illness ^{4, 7} 	Possibly *
Impaired ability to absorb or utilise nutrients ²	<ul style="list-style-type: none"> ○ Diarrhoea, ○ Vomiting, ○ Gastrointestinal disorders ○ Certain disease states (e.g. Crohn's disease, IBD) ○ Medications ³ 	Not specifically Not specifically Not specifically Not specifically Yes ³

¹Brotherton et al. 2010.

²Albreda et al. 2006.

³Stanga, 2009.

⁴Saunders et al. 2010.

⁵Ekberg et al. 2002.

⁶Germain et al, 2006.

⁷Richardson and Davidson, 2003.

⁸Morley, 1997.

* Depending on the underlying cause/ co-morbidity associated with dysphagia

In severe cases malnutrition can affect well-being and clinical outcome (Elia 1993) therefore managing nutritional status in hospitals is crucial for recovery. Also, in a reciprocal relationship, malnutrition can further contribute to the severity of dysphagia as reduced food intake further increases the risk of reduced functional status (Croghan and Pasvogal 2003), which may include swallowing function. Meeting food and nutrient requirements will also reduce the risk of the associated

complications such as reduced muscle function and apathy which could negatively impact on QOL (Smoliner et al. 2008). Clearly, ensuring adequate nutritional intake, by the best means possible, is therefore imperative to successful recovery.

Malnutrition is not only associated with reduced QOL (Rasheed and Woods 2013) and potentially serious health consequences (reviewed elsewhere (Green 1999; Corish and Kennedy 2000; Neumann et al. 2005; Albreda et al. 2006; Saunders et al. 2010), summarised in Table 1.3), but it is also very costly with estimates that disease related malnutrition (in hospital, domestic and community settings) costs the UK in excess of £13 billion a year (Brotherton et al. 2010). The substantial costs associated with this preventable and treatable condition, further adds to the argument for the need to develop effective management strategies to ensure adequate nutritional intakes in those with, or at risk of becoming malnourished.

Table 1.3: Commonly reported effects and consequences of malnutrition

Effect	Consequence^{1,2,3,4}
Reduced muscle strength and fatigue ^{1,3}	Muscle wasting (which may affect respiratory function, cardiac function and inactivity) Poor muscle function may result in falls
Compromised immune response ⁴	Impaired ability to fight infection
Impaired wound healing ^{1,2}	Increased wound-related complications
Impaired ability to regulate salt and fluid ¹	Predisposes over-hydration, or dehydration
Specific nutrient deficiencies ¹	E.g. Anaemia (iron and B ₁₂), scurvy (vitamin C)
Impaired psycho-social function ¹	Apathy, depression, introversion and loneliness

¹Brotherton et al.2010; ²Albreda et al. 2006; ³Saunders et al. 2010; ⁴Lesourd and Mazari 1997.

1.2 Management of malnutrition in hospitals

It is clear that dysphagia is associated with malnutrition (section 1.1.2). Due to the associated cost and morbidity that can occur with malnutrition, its management is a crucial aspect of patient care. The “best practice” management of malnutrition is outlined in the National Institute for Health and Care Excellence (NICE) Clinical Guideline 32 Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition (NICE 2006). This guideline is followed all over the UK although individual discretion of the healthcare professional (in collaboration with the patient and carer) prevails. An overview of the systematic approach to managing malnutrition can be seen in Table 1.4.

Table 1.4: Systematic approach to evaluation and treatment of malnourished patients (NICE, 2006)

Step	
Identify nutrition risk or presence of malnutrition	NICE recommend using the Malnutrition Universal Screening Tool (MUST)
Consider enrichment of food diet/add oral nutrition supplements	Enrichment of a regular food diet by adding sources of carbohydrate, protein, and/or fat may be appropriate as an initial treatment strategy. ONS may be given in combination with regular food, or used as sole source feeding when intake of regular food is limited.
Use supportive enteral tube feeding	Nutrition can be given as enteral tube feeds when ONS is impossible or inadequate.
Use parenteral nutrition	Parenteral nutrition may be used either alone or in combination with enteral nutrition when the gastrointestinal tract is compromised.

The first step to successfully managing malnutrition, is by identifying those who are malnourished, or those at risk of malnutrition (nutritional screening). Following nutritional screening, those identified as undernourished, and those at risk of becoming undernourished, should be referred to a dietitian for nutritional intervention which may include the prescription of oral nutritional supplements (ONS) (discussed in section 1.2.2) as part of their overall nutritional care plan. It is in fact recognised that those with dysphagia are at risk of malnutrition and thus after a swallowing problem has been identified these individuals are referred to a dietitian for nutritional care plan.

Methods to improve or maintain nutritional intakes are known as nutrition support. These include oral nutrition support (e.g. enriched food, additional snacks and/or sip feeds) which is of relevance to this thesis. When oral nutrition is tolerated, food should be considered the first line of intervention and only when nutritional requirements cannot be met by food and fluid alone, other interventions should be considered (Food and Nutritional Care in Hospitals (Department of Health and Children 2009); The Nursing Care Standards for Patient Food in Hospital (Department of Health, Social Services and Public Safety 2010)).

In fact, where people can consume food, proprietary oral supplements and artificial nutrition support techniques should only be used as intended, (*i.e.* to *supplement* and *support*), and not be a substitute for the adequate provision of normal food. Oral nutrition support is preferred because this route of feeding takes advantage of the gastrointestinal tract, as well as the antibacterial properties of saliva (Hamilton and Boyce 2013). Furthermore, the majority of patients in hospital and members of the

community gain their nutritional intake orally, through food. The total number of main meals requested by in-patients during 2012-13 was 142.3 million (NHS 2013, Health Estates and Facilities statistics 2012-13) alluding to the high uptake of food provision services in our hospitals. It is therefore central to recovery that food provision services are adequate in terms of nutrition, quality and quantity (including variety).

It is acknowledged that in practice some patients will not tolerate oral nutrition and in these cases will require nutrition from other delivery methods. Such artificial nutrition support include enteral nutrition (e.g. the delivery of a nutritionally complete feed directly into the gut via a tube) and parenteral nutrition (e.g. the delivery of nutrition intravenously). Although these are not a focus of this thesis and thus will not be reviewed here, where clinically indicated they can be effective means of achieving nutritional goals, potentially improving clinical outcome (Gramlich et al. 2004; Stratton and Elia 2007; Milne et al. 2009; Baldwin and Weekes 2012; Cawood et al. 2012).

1.2.1 Food based oral nutrition support strategies

Despite the scant evidence surrounding the benefit of food based strategies to support their use for the nutritional management of malnutrition, it is advocated that where possible, “food first “approaches are recommended (NICE 2006; Essence of Care (Department of Health 2010a);The Nursing Care Standards for Patient Food in Hospital (Department of Health, Social Services and Public Safety 2010). Applied localised service delivery strategies are focussing more on promoting oral nutrition

using food based approaches in an attempt to reduce the inappropriate prescription of ONS. Examples of these include; Focus on Undernutrition (County Durham and Darlington NHS 2014) and the NHS Bedfordshire Food First strategy (SEPT 2014).

“Food first” approaches to manage nutrition may be in the form of advice on food choice, meals, snacks, nourishing drinks and food enrichment (BAPEN 2012b). Dietary advice is frequently recommended as the first means of nutritional intervention. However a recent review focused on assessing the evidence base for this and concluded that there is a lack of clinical data to support this strategy to combat malnutrition (Baldwin and Weekes 2012). This review did however report that the nutritional intervention (dietary counselling alone) was apparently associated with significant improvements in energy intake (values not reported). It is acknowledged that heterogeneity between studies, however, was high suggesting that this improvement may be confined to some of the patient groups. There was no significant difference in energy intakes between the groups receiving ONS plus dietary counselling compared to usual care (mean difference 158 kcal; 95% CI = -66 to 382, $p = 0.17$). Authors, however acknowledged a lack of correspondence between improvements in energy intake and weight gain (which was demonstrated to be greater with ONS plus dietary counselling compared to usual care (mean difference = 1.7 kg; $p = 0.0001$; 95% CI = 0.86–2.55)) which was thought to suggest that errors in the reporting and analysis of food intake data occurred.

Provision of high energy snacks can also be implemented to improve food and energy intakes. Turic et al. (1998) found that in long term care patients the additional provision of between meal snacks (three times a day) improved daily energy intakes

by 28% (346 kcal) compared to when no snacks were provided. This strategy for improving energy intakes may be particularly useful in older adults who have shown to inadequately compensate for additional energy intake compared to younger adults (Rolls et al. 1995a; Appleton et al. 2011) potentially promoting net additional nutritional intake. Interestingly, compliance to the additional snacks in the study by Smoliner et al. (2008) was variable, with provision and consumption of these lasting 8.8 ± 4.5 weeks compared to the enriched meals which were consumed for the full 12 week intervention period. Reasons for non-compliance were not reported, however may have been due to the fact that patients were required to consume more food as snacks (resulting in the consumption of greater total food volumes). This is why energy enrichment of food may be beneficial, as it allows an increase in energy (kcal) without the need to increase the volume of food.

In fact, those at risk of malnutrition (often referred to as “nutritionally vulnerable” (Scottish Government 2008)) often require, or are prescribed a meal that is described as being “energy dense”. This is to ensure energy requirements are met, and ideally help with recovery. Increasing the energy density results in a meal that has a greater number of calories per portion, which in theory should result in a greater intake of energy, once the same portion is consumed. Whilst most experimental studies investigating energy density on intakes (section 1.6.2) are conducted with the aim to reduce intakes, some evidence exists suggesting it may have benefit for increasing energy consumption in those with poor food intakes (Odlund Olin et al. 1996; 2003; Gall et al. 1998).

These studies include cohort studies and clinical studies where patients are restricted by their conditions and treatment plans. Therefore these studies are less controlled than experimental studies and thus introduce confounding variables which can lead to misinterpretation of the results. Furthermore, although the studies had similar objectives, they cannot be directly compared as they were conducted using different sample groups, and also used different meals with varying levels of energy enrichment and different macronutrient profiles.

Individually, they do suggest the potential of enrichment as a strategy to improve intakes in vulnerable groups. For example; Gall et al. (1998), demonstrated significant increases in daily energy intakes of 17.5% (246 kcal) when patients (n=62) were offered increased choices of enriched meals throughout the day (with double cream, and dried skim milk powder) and additional snacks (cake, cheese sandwich) compared to when the same meals without enrichment or additional snacks were offered to another group of patients with similar characteristics (n= 81). Odlund Olin et al. (2003), found a 36 % increase (504 kcal, $p < 0.001$) in daily energy intake in an experimental group of 17 nursing home residents (NHR) during a 12 week testing period where they received enriched meals (with butter and cream) compared to the two week pre-test period where they (the same study group) received the same meals, but without enrichment.

This trend of increased energy intakes with enrichment is however not consistently demonstrated. Smoliner et al. (2008) found that daily energy intakes in a group of nursing home residents receiving a standard diet (n=30) and a group receiving an enriched version (with protein powder, rapeseed oil and cream) of the standard diet (n=22) plus two additional snacks high in protein and energy, were not significantly

different for energy intake ($p>0.05$) although, protein intakes were significantly higher (+12 g/d (62.6 ± 11.5 g versus 74.3 ± 18.3 g, $p=0.007$)) in the enriched group. Perhaps the higher protein intakes consumed within the energy enriched diet subsequently impacted on energy intakes due to the satiating effect of protein (Stubbs and Elia 2001; Ryan et al. 2003; Benelem 2009).

Silver et al. (2008), investigated if providing lunch meals with higher energy density (2.2 kcal/g versus 1.1 kcal/g) in a home-delivered meal programme (in older adults (mean (SD) 84.4 ± 1 years)) resulted in higher energy intakes over 24 hours. The more energy dense meal was enriched through the addition of various ingredients such as eggs, almonds and mayonnaise. The meals therefore differed across a range of nutrients, including protein content. The enriched meal contained an extra 10 g of protein compared to the standard meal. Consumption of the enriched meal resulted in significantly higher energy intakes at lunch of 359 ± 17 kcal (regular meal: 415 ± 16 kcal versus, enriched meal: 774 ± 33 kcal) although there was no difference in the quantity (g) of meal consumed.

Also, regardless of the consumption of an enriched lunch or a standard lunch there was no difference in the quantity (g and kcal) of meals consumed at both breakfast and dinner. Therefore, despite the higher protein content of the enriched meal there was no apparent induced satiety leading to a reduction in subsequent intakes. Total daily energy intake therefore remained significantly higher on the days that enriched meals were served (total mean increase of 453 ± 16 kcal). This study further demonstrates the potential of the provision of higher energy dense meals (enriched

with an additional 1.1 kcal/g), for improving energy intakes in a 24 hour period in older adults, despite the higher protein content.

Another crossover study investigated the usefulness of enrichment for maximising the nutritional intakes of patient groups in geriatric wards (Odlund Olin et al. 1996) and found that enriching main meals (with store cupboard ingredients such as cream, oil, margarine and milk) to increase their energy content (by 50%) led to prolonged satiety and reduced between meal food intakes. It was noted that the protein content (average weekly distribution) of the meals provided for the enriched meals was higher (101 g versus 80 g) compared to the standard meals and this may have influenced satiety, although actual protein intakes were not reported therefore this is not conclusive. Whilst net energy intake across the day was significantly increased (450 kcal/day, $p < 0.0001$), the potential of energy compensation needs to be evaluated in order to determine the overall effectiveness of providing an energy dense diet.

Interestingly, a study by Rolls et al. (1995a) investigated the ability of the elderly to regulate their short term food intake and demonstrated that older adults are less able to correctly adjust and compensate for altered energy intakes. Subjects were given yoghurt preloads of varying macronutrient content (low-fat, low-energy: 962 kJ/ 229 kcal, high-fat, high-energy: 2134 kJ/ 508 kcal, high-carbohydrate, high-energy: 2134 kJ/ 508 kcal) or no yoghurt preload, and were then asked to eat a self-selected buffet style lunch. The results demonstrated that the older subjects (68.9 ± 1.6 years) did not compensate as well as the younger subjects did (24.3 ± 1.2 years). In fact, it was found that the older adults tended to overeat at the self-selected lunch after the

preloads compared to when no preloads were consumed such that energy intake (lunch plus preload) was higher on the days preloads were consumed. When subjects did not receive the yoghurt preloads, test meal energy intakes demonstrated that the elderly consumed significantly less energy intakes (kcal) at the lunch meal (1262 kJ/ 300 kcal, $p<0.05$) than the younger individuals under the same conditions. It can be argued that these results show that the elderly have a reduced ability to regulate food intake which can lead to both under and over consumption. This may however be advantageous in terms of the provision of enriched energy dense meals, as the findings demonstrate that despite the consumption of high energy preloads these older individuals did not reduce their energy intakes later to compensate, which resulted in higher energy intakes on the preload days.

Another strategy to encourage energy intakes in those receiving meals which may be nutritionally diluted (such as a TMD meal) is the provision of meals of greater portion size in an attempt to counteract the nutritional dilution by providing a greater opportunity to consume energy. Despite the fact that a review conducted by Kral and Rolls (2004) and a subsequent study by Rolls et al. (2006) demonstrated that increased portion sizes of food leads to significant increases in daily intakes in healthy adults, this approach may not benefit those with dysphagia and/or a reduced appetite. As already mentioned (section 1.1.2) reduced appetite is a common complaint in a hospitalised population (Scottish Government 2008; Muscaritoli et al. 2010) and also in the elderly (Stanga 2009). Whilst studies have not specifically measured subjective appetite responses in dysphagic patients receiving a TMD; Ekberg et al. (2002), found that 33% of patients (from the UK arm of study) subjectively reported to have a loss of appetite after their diagnosis of dysphagia. It is

for this reason that a preferred strategy may be to enhance the energy content of meals without the need to increase the volume or portion, essentially increasing the energy density of the meals to allow for a greater consumption of energy whilst consuming similar volumes of food.

The provision of a large variety of food choice in order to ensure that all needs are met is another recommended strategy to treat malnutrition, as it has been shown that increasing the variety of foods served has the potential to improve intakes (Brondel et al. 2009). Norton et al. (2006a) found energy intakes at a lunchtime eating occasion improved by 14% (282 kJ/ 67 kcal) with provision of a variety of sandwich fillings compared to one single filling,. However this was a relatively small increase in energy intakes (not clinically relevant) and was observed in young, healthy, normal weight subjects and results may not be consistent with an older or unwell population.

Hollis and Henry (2007) did however demonstrate that older adults, similar to younger subjects, consumed more (267 +/- 91 g compared to 215 +/- 78 g) of a sandwich meal made up of four filling varieties compared to a monotonous sandwich meal (*i.e.* the same filling throughout). This difference was however not statistically significant, and as the differences in energy intake were not reported it is unclear if this increase in absolute intake (g) with variety would become clinically significant. Still, standards state that patients must be offered a choice of food that meets their dietary needs (NHS QIS 2003; Scottish Government 2008). Reflecting this, Audit Scotland (2006) reported that hospital catering services are offering greater choice of meals. Similar standards are in place in care homes (Scottish Government 2007, Care Commission; Standard 13).

An alternative approach; using the addition of sauces, has been shown to improve short term energy intakes in older adults (Appleton, 2009). Mean increases of 72 kJ/17 kcal (915 kJ/ 218 kcal \pm 245 kJ/ 58 kcal without sauce, versus 987 kJ/ 235 kcal \pm 251 kJ/60 kcal with sauce ($p < 0.05$)) were observed with the addition of sauce to a meal. Whilst this increase in energy intake (+ 17 kcal) is statistically significant, its clinical significance is questionable, as this is a very slight increase and may have even been related to measurement error. It does however demonstrate that the addition of sauces may be a useful strategy to use alongside other proven strategies to encourage higher energy intakes. The compensatory effects on subsequent energy intakes were not investigated in this study therefore it is unclear what effect increased energy intake from the addition of sauce had on daily energy intakes.

Saying that however it is thought that this addition of sauce was unlikely to greatly impact on subsequent intakes as there was only a small increase in energy intake (+17 kcal) at the single meal occasion. The addition of sauces may also have a role to play in enhancing meals (in terms of texture, flavour and energy content) including TMDs, which are often prepared with the addition of non- caloric fluids, which can reduce the nutrient density of the meal. Using a nutrient containing sauce, (*i.e.* gravy) could be useful to achieve desired textures whilst reducing the impact of nutrient dilution observed with the addition of non-caloric liquids.

The use of flavour enhancers may be beneficial for promoting intakes. Studies have shown a positive effect on food intakes following the addition of flavour enhancers and natural flavours (such as roast beef, ham, natural bacon, prime beef, cheese and maple flavours (Schiffman and Warwick 2003)) based on the fact that they can help

to compensate for perceptual losses and improve food palatability and acceptance (Schiffman and Warwick 1993). Henry et al. (2003), also demonstrated that energy intakes can be improved (13-26% (235 kcal - 835 kcal) over three days) through the addition of natural flavours (such as ginger and rice wine, ginger and garlic, sesame oil, oyster sauce, spiced soya sauce and soya bean paste) in hospitalised elderly patients.

The development of meals with additional flavours may therefore be an effective strategy to adopt in hospitals; however this would need to be evaluated further in order to determine appropriate levels that are tailored to specific population's dietary preferences. It is also necessary to ensure that the addition of flavours does not result in further reduced intakes for some individuals who may not like stronger flavours, or have certain food intolerances.

Aside from being the most physiological method of feeding, food based strategies (when safe, and tolerated) may offer additional benefits compared to other nutrition methods. Unfortunately the evidence base features only few studies specifically investigating food based oral strategies for managing nutrition. Table 1.5 provides an overview of potential additional benefits (and hypotheses to which future studies could investigate) associated with food based strategies; however there is a need for well controlled RCT's to be conducted which can demonstrate their potential in overall nutritional management.

Table 1.5: Summary of the potential benefits of food based strategies

Possible benefit	Rational/hypothesis
Nutrition is just one aspect of eating	Dining also enables social interaction, celebrations. Pleasure can also be acquired from food (<i>i.e.</i> sensory feedback)
Increased choice and variation	More variation in meals available compared to complete nutrition options (EN, PN and sip feeds).
Compliance	Greater variation therefore less likely to grow bored or experience flavour fatigue (Bolton 1992). Food is arguably more universally accessible as there is no need for prescription
Greater ease (and therefore perhaps also more community friendly)	No special training required or additional support (in the most case)
Cost	In hospitals, more is spent on supplements (than food ingredients) despite the fact that the majority of inpatients require food (80-100% of patients meet their requirements through food (NHS half yearly report 2013))
Familiarity	People are familiar with food therefore no need to introduce new methods of nutrition. (Beneficial in older adults who may be neophobic).

In summary, from the food based studies that have been conducted, increases in energy intakes have been observed (Schiffman and Warwick 1993; Turic et al.1998; Henry et al. 2003; Norton et al. 2006a; Hollis and Henry 2007) demonstrating their potential. In hospitals, where the prevalence of malnutrition is greatest, most patients seek to meet their requirements through food (Health facilities Scotland, 2012). The high reported level of food waste in hospitals (Barton 2000) implies that food provision services are not adequate. However this is not necessarily the case and

needs to be explored further before food based strategies are disregarded. For most, requirements should be capable of being met through food, yet more money is spent on provision of supplements.

It is true that the estimated 24-35% of patients who are thought to be malnourished on admission to hospital (BAPEN 2012a) may benefit from additional nutritional support strategies (e.g. ONS, discussed section 1.1.5). However it is reiterated that for those who tolerate oral nutrition, food based strategies such as enrichment offer the potential to enable patients to meet their energy requirements such that ONS would no longer be required. With a combination of more studies conducted to determine and evaluate the potential of food based strategies to manage malnutrition, along with an improvement in food provision services, nationwide, it is hoped that malnutrition can begin to be tackled, cost effectively.

1.2.2 Improving energy intakes using ONS:

In some individuals the use of ONS alongside a food based strategy may further encourage increased intakes. In fact, when patients cannot meet their nutritional requirements with standard hospital food or enriched diets, supplementation with sip feeds must be considered. ONS are classed as ‘border-line substances’. They can only be prescribed on an NHS prescription if the patient’s condition falls into a specified Advisory Committee on Borderline Substances (ACBS) category (Table 1.6).

Table 1.6: Advisory Committee on Borderline Substances (ACBS) indications for ONS

Standard ACBS indications are	
<ul style="list-style-type: none"> • Dysphagia • Disease related malnutrition • Pre-operative preparation of malnourished patients 	<ul style="list-style-type: none"> • Short bowel syndrome • Intractable malabsorption • Bowel fistula • Inflammatory bowel disease • Following total gastrectomy

ONS can have beneficial outcomes in terms of morbidity and complications particularly in acute settings and acutely ill older adults (Stratton and Elia 2007). In one study daily energy intakes at three weeks improved by 46 % (597 kcal) with the inclusion of high energy supplements between meals, compared with increases seen with provision of snacks (28 % (346 kcal)) (Turic et al. 1998). A meta-analysis evaluating protein energy supplementation in adults (including 30 randomised controlled trials, involving 2062 patients) demonstrated that nutritional parameters improved in the supplemented patients (Potter et al. 1998). The parameters reported included; change in weight (mean difference for weight change showed benefit from supplementation (2.06%, 95% C.I 1.63% - 2.49%), but was complicated by heterogeneity) however this change in weight (*i.e.* 2%) is not considered clinically significant (Stevens et al. 2006).

A more recent Cochrane Review by Milne et al. (2009) evaluating the effects of protein and energy supplementation (in 10,187 elderly people at risk of malnutrition), concluded that supplementation produces small, but consistent weight gains (n=42 trials: mean difference for percentage weight change showed a benefit of supplementation of 2.2% (95% confidence interval (C.I: 1.8 - 2.5.)). Their review

found no evidence of improvement in functional benefit (for example cognitive functioning, muscle functioning, mobility, ability to perform activities of daily living), or reduction in length of hospital stay with supplements (mean difference was -0.8 days (-2.8 to 1.3) with significant heterogeneity). It should be mentioned however that the FOOD trial (2005) which demonstrated a slightly longer average stay for supplemented stroke patients dominated the results for the meta-analysis of length of hospital stay with supplementation. Also, this review contained a number of studies deemed to be of poor quality however, therefore should not be used as a definitive basis for routine clinical use. These studies may however, be used to provide guidance within the clinical setting.

Despite their demonstration to potentially improve nutrient intakes and nutritional parameters, long term compliance to ONS can be an issue, possibly due to flavour fatigue (Bolton et al. 1992). However a recent review (Hubbard et al. 2012) of 46 studies (total patients; n= 4328, total patients receiving ONS; n= 2282) found that overall compliance to ONS was good, reporting 77% (20.9-100%) compliance across a wide variety of patient groups in hospital and community settings. It should be noted that there was a large variability in the level of compliance and also the quantity, and resulting energy content of supplements prescribed. Mean consumption was calculated to be 433 kcal/day (compared to the pooled mean ONS energy prescription of 562 kcal/day ranging from 237 to 1080 kcal/day), however varied from 144 kcal/day to 1045 kcal/day which may have influenced compliance. It should also be considered that the results presented are reporting means and may not necessarily reflect the efficacy of ONS on an individual basis.

Despite this, the review does demonstrate that the provision of ONS, if consumed, may improve nutritional intakes. A consideration with ONS is the timing of administration especially since Wilson et al. (2002) demonstrated that in elderly patients the administration of dietary supplements may be more effective when given between meals rather than with meals. This is due to the longer satiating effects with consumption of high fat and high protein supplements in older subjects compared to younger subjects (Wilson et al. 2002). It is important that the additional energy provided with supplementation (and indeed also with food enrichment), does not cause a subsequent reduction in energy intakes at later eating occasions, thereby negating any benefit in energy intake.

There is a lack of studies evaluating the cost effectiveness of supplements, which is another fundamental consideration when considering their routine use and prescription. A review (Russell 2007) aimed to evaluate the cost effectiveness of supplementation (ONS) in hospital, comparing supplementation to usual care. It was decided that the more cost- effective strategy would be the one that resulted in greater value for money. Despite the lack of studies available specifically assessing cost effectiveness, it was concluded that when costs are applied to clinical outcomes (reported in published studies such as reduced length of hospital stay and incidence of complications), it can be demonstrated that cost savings can be achieved through use of ONS in selected patient groups (Russell 2007). It should be highlighted however that costs were derived from the amount consumed, rather than prescribed, therefore not accounting for the waste associated with supplement provision. Costs were also fixed as £0.20 per unit regardless of brand or size of serving. These estimations may falsely suggest lower costs than actually associated with

supplementation. This is particularly true when considering their use outside the clinical setting, for example in the community where ONS cost approximately £3.00 per 220 ml unit (based on the price of a case (36 units) of Ensure Plus).

ONS certainly have their place, however should be used as they are intended; to supplement the diet, therefore when food is tolerated they should not be a substitute for the adequate provision of normal food. An evidence base continues to be built surrounding the use of supplements, however the same investigations need to be conducted in comparison to food based strategies to attain a balanced view of all of the potential nutritional management techniques. Further the fact that a number of the studies conducted surrounding supplementation are supported, or associated with large nutritional supplements producers, brings the motive for conducting these studies into question. More work is justified in the area, particularly to investigate the interactive effects of different nutritional support strategies on intakes, for example the efficacy of using ONS alongside food based strategies. As food based strategies are the interest of the current thesis, and since there is a high level of food waste in hospitals (Barton 2000) thus bringing the adequacy of food provision services into a question, an overview of catering practices and food provision in hospitals ensues.

1.3. Catering practices and food provision in hospitals (UK).

The NHS aims to improve health and prevent disease (Davies 2008). Food provision, which is accessible, and of sufficient quality to enable adequate consumption, to contribute to achieving this goal is vital. After all, the public sector, including the NHS, has a “Corporate Social Responsibility to offer healthy, nutritious food in its

institutions and to lead by example in improving the diets of its staff and patients” (Department of Health 2005). Despite this statement, hospital food provision (in some sites), whilst is steadily improving continues to be identified as an area for improvement within the care of patients (Health Facilities Scotland 2012). Even today, catering services are grouped within the non-clinical aspects of care such as cleaning, training and building maintenance (Radcliffe Health 2012).

Adequate food provision services however play a central role in patient recovery and health outcomes. It should be considered however, that provision is only one aspect of ensuring patients’ nutritional goals are met. After all, if the food that is provided is not consumed, no nutritional benefit will result. Food provision services must therefore consider the nutritional needs of patients, as well as combating barriers to achieving adequate food consumption (section 1.3.3).

1.3.1 A history of the policies relating to hospital food provision in the UK:

Hospital catering has been an important focus within healthcare for a long time, as evident with the founding of the Hospital Caterers Association (HCA) in 1948 which is still in operation today. One focus of the HCA is the promotion, development and improvement of the standards of catering in hospitals and healthcare establishments. The HCA is not the only driving force behind the improvement of healthcare catering. In fact, over the years a number of guidelines and voluntary initiatives (Table 1.7) have been introduced with the aim to improve food and nutrient provision in hospitals, all over the UK. Unfortunately, these have mainly failed as evident by reports of persisting malnutrition in hospitals and care homes in the UK

(Age UK (2006; 2010), BAPEN (2007; 2010; 2012a), and the Care Quality Commission: Dignity and nutrition inspection programme (2011)).

Further these failed initiatives which include the recruitment of celebrity chefs, and development of guidelines generated from a limited evidence base, take away from the overall budget allocated to hospital food provision. It is likely that the voluntary nature of these initiatives contributed to their failure, calling for the need for nutritional standards to emerge. Mandatory standards are now in place in Scotland (Scottish Government 2008) and Wales (All Wales nutrition and catering standards for food and fluid for hospital inpatients, Welsh Government 2010 (replacing the Welsh Government nutrition and catering Framework, 2002)). England are yet to issue mandatory health (and sustainability) standards for hospital food although this is currently being debated in parliament (November 2013) and may be introduced as part of the Health and Social Care (Amendment) (Food Standards) Bill.

Table 1.7 History of institutional food policies and guidelines

Initiative	Result
<p>1995: Nutritional Guidelines for hospital catering (Department of Health 1995) Launched in response to the publication of; “A Positive Approach to Nutrition as Treatment” (King’s Fund 1992) which identified poor nutrition as a problem amongst hospital patients</p>	<p>Largely unsuccessful as initially evidenced by results from a survey assessing hospital catering demonstrating that some patients were still not consuming enough food or drink in hospital (Community Health Council 1997).</p> <p>These guidelines have been withdrawn and are now no longer accessible.</p>
<p>2001: “The NHS Plan: a plan for investment, a plan for reform” (Department of Health 2001a). Outlined key changes to be made to modernise the running of the NHS that also respond more to patient’s needs</p>	<p>Within this investment plan, hospital food provision was identified as not being as “good enough standard”, such that an additional £10 million a year was pledged to specifically improve the service.</p>
<p>2001-2002: “Better Hospital Food initiative” (Hospital Caterers Association 2001) “Essence of care guidelines (Department of Health 2001b)</p>	<p>These were also largely unsuccessful with malnutrition still prevalent in UK hospitals. Reflecting their lack of success, the Better Hospital Food initiative was scrapped in 2006, and in a review assessing the Essence of care, it was reported to be largely misunderstood, or even known about (Hartley 2004).</p>
<p>2002: The Council of Europe (COE) created a network to collect information on nutrition programmes in hospitals. During the review, five key areas were identified as deficiencies in food provision in European hospitals. These were; lack of clearly defined responsibilities, lack of sufficient training, lack of influence on menus from patients, lack of co-operation among staff groups and lack of involvement from hospital management.</p> <p>Welsh Government nutrition and catering Framework (2002)</p> <p>National Association of Care Catering (NACC) was named (previously the Advisory Body for Social Services Catering (ABSSC) set up in 1985).</p>	<p>In 2003, The Council of Europe produced a resolution on hospital food; “Food and Nutritional Care in Hospitals: How to Prevent Undernutrition”. This outlines 10 Key considerations to achieve good nutritional care in hospitals, and acts as the basis for many national and local policies and guidelines surrounding nutritional care today.</p> <p>This was later enhanced to include specific nutrition standards (All Wales nutrition and catering standards for food and fluid for hospital inpatients, 2010)</p> <p>This group is still in operation today and aims to promote and enhance the standard of catering within the care sector.</p>
<p>2003 Scotland: NHS QIS Clinical Standards for Food, Fluid and Nutritional Care in Hospitals These applied to all hospital in-patients, including those in community hospitals and long-term care facilities.</p>	<p>Standards 3, 4 and 5 specifically aim to address the risks of malnutrition in hospital patients. These standards are still in place and largely followed today.</p>

Initiative	Result
<p>2006 (Nationwide) The National Institute for Clinical Excellence (NICE) published Nutrition Support for Adults: Oral Nutrition Support, Enteral Tube Feeding and Parental Nutrition - Methods, Evidence and Guidance (NICE 2006) (described in detail in section 1.3).</p>	<p>These recommendations re-iterate the need for regular nutritional screening, multi-disciplinary working and education and training in the hospital setting. They also state that “adequate quantity and quality of food and fluid is available in an environment conducive to eating and there is appropriate support.</p>
<p>2007 (England) Royal College of Nurses (RCN) launch the “Nutrition Now! Campaign”.</p> <p>The Department of Health also launched the Nutrition Action Plan</p> <p>2007 (Northern Ireland): Get your 10 a day! The Nursing Care Standards for Patient Food in Hospital was launched in Northern Ireland.</p>	<p>This led to the publication of more voluntary principles (RCN Principles for Nutrition and Hydration) however this campaign was cancelled in 2009 due to lack of take up</p> <p>This was supported by the launch of online nutrition training (in 2008). This “training” included factsheets and ideas to help patients meet their nutritional needs. It is still accessible today, hosted and maintained by the Social Care Institute for Excellence.</p> <p>This was later (in 2012) supported by Promoting Good Nutrition! A Strategy for Good Nutritional Care for Adults in all Care Settings in Northern Ireland, which aims to build on Get Your 10 a Day to include all health and social care settings including peoples own homes (Department of Health, Social Services and Public Safety 2012). This guidance does not outline specific nutrient standards but rather includes the recommendations issued by the Council of Europe (Council of Europe 2003).</p>
<p>2008 (Scotland) Food in Hospitals (Scottish Government, 2008) The guidance was the first to cover nutrient and food based standards which provide for the needs of a diverse hospital population of all ages, both nutritionally at risk and nutritionally well, and those with particular therapeutic and cultural requirements.</p>	<p>Based on the standards in place in Scotland, Food in Hospitals (Scottish Government, 2008), Wales produced the All Wales nutrition and catering standards for food and fluid for hospital inpatients (Welsh Government, 2010)</p>
<p>2012 (England) More guidelines and principles (<i>the digest for patient nutrition and hydration</i> (BDA 2012b) and “<i>New principles</i>” for hospital food in England (Department of Health 2012a)) issued in England however the Department of Health denies that “standards are needed” (Department of Health 2012b).</p>	<p>Most recent developments include the consideration of the introduction of hospital food provisions standards in England which is currently being debated in parliament and may be introduced as part of the Health and Social Care (Amendment) (Food Standards) Bill.</p>

1.3.2 An overview of the catering systems in place in hospitals

Each country of the UK has chosen to structure its National Health Service differently (Harker 2012), therefore where information is available; findings from all four countries of the UK have been reported separately. Unfortunately, not all countries have recently conducted audits assessing catering systems therefore some, of the findings may be outdated.

Cost is a major consideration when developing public sector food provision services, as the NHS operates under tight budgets. Further, as part of the government's white paper, 'Equality and Excellence – Liberating the NHS' (Department of Health 2010b) the NHS is required to cut £20bn from its annual budget by 2015. The NHS budget for 2012/13 was around £108.9bn, of which approximately 20% is allocated to cover the combined costs of building maintenance, training programmes, medical equipment, catering and cleaning. The amount actually allocated specifically to hospital catering services is unknown. Although according to NHS Hospital and Estates data 2012/2013, the gross cost of patient food services for all NHS Trusts (in England) was £540,690,577. Half of this money, (a total of £270,345,288.50) was spent on food ingredients (NHS 2013, Hospital and Estates data 2012/2013).

In 2003/2004 hospital catering in Scotland cost £73 million (representing 1% of total spend on the NHS) (ISD 2005) with the average cost of daily food and drink provided to patients (excluding operational costs) being £2.34 (variation not reported) per day (Audit Scotland 2006). It is likely that due to the increases in cost of wages (*i.e.* increased minimum wage) in recent years, that this has resulted in smaller proportions of the budget being allocated to the cost of food. Most recent

accessible data from Northern Ireland reported that food provision costs (per patient, per day) varied from £1.26 to £2.75 (Department of Health, Social Services and Public Safety 2001). Again, this data is from a considerably long time ago, and thus may not accurately reflect catering expenditure today. Although as the values solely reflect the cost of food and drink spent per patient per day they may not have changed considerably, as most of the increases in costs associated with hospital food provision were reportedly due to, staffing costs (which are estimated to be more than twice the cost of food and beverage provision (Audit Scotland 2006) or 60% of the total NHS budget (Radcliffe Health 2012)).

The reported costs presented so far also do not include operational costs, expenditure on supplements (estimated to be more than £300 million (Health and Social Care Information Centre (HSCIC) 2012)) or the cost of initiatives introduced to improve the catering provision (which as read in section 1.3.1. Table 1.7, have largely failed) estimated to be £54 million over the past 21 years (Campaign For Better Hospital Food 2013). Data from the Health and Social Care Information Centre (HSCIC) shows that the NHS spent £321,746,579 on nutritional supplements for hospital patients in 2012, comprising: £224,785,117 on enteral nutrition, £96,961,462 on foods for 'special diets' (HSCIC, 2012).

Therefore it can be concluded that in 2012, the NHS spent more than £300 million on nutritional supplements for patients who are malnourished, have specific dietary requirements or are lacking in nutrients, yet spent less than this amount on food for patients (estimated to be £270,345,288 (NHS Hospital and Estates data 2012/2013)). This is despite the fact that 80-100% of patients in hospital require nutrition from food (Health Facilities Scotland, 2012) and that it was reported that the total number

of in-patient main meals requested by in-patients during 2012-13 was 142.3 million (Health Estates and Facilities statistics 2012-13).

To put these expenditures in context, the annual expenditure on managing patients with medium or high risk of disease-related malnutrition (specifically in hospitals) has been estimated to be approximately £3.8 billion (Elia et al. 2006 (on behalf of BAPEN)). The annual cost to the NHS of food wasted from ‘unserved meals’ was reported to be £18 million, or an average of £55,000 per trust in England and Wales (Audit Commission 2001). Again these figures are quite dated and it cannot be assumed that this level of waste from “unserved meals” still exists today. Other reports estimated the total value of food wasted (which includes unserved meals and also served, but uneaten meals) is £45 million in England alone (Allison 1999). This is rather alarming; especially when the total cost of food provided is considered. In fact, this crudely suggests that almost 20% of the money spent on providing hospital food (ingredients) is not being utilised.

The logistics of food provision is certainly another challenge therefore a number of systems to ensure adequate food provision services are in place throughout the UK. However it should be acknowledged that as recent data describing the services used is limited, the data presented here does not necessarily reflect practices in place today. For example, the data from Scotland is from 2006, two years before the introduction of the new food provision standards (Scottish Government 2008). Introduction of these new standards may have resulted in amendments to overall catering services however more recent data are not available. Figure 1.1 outlines usual food provision services in the UK.

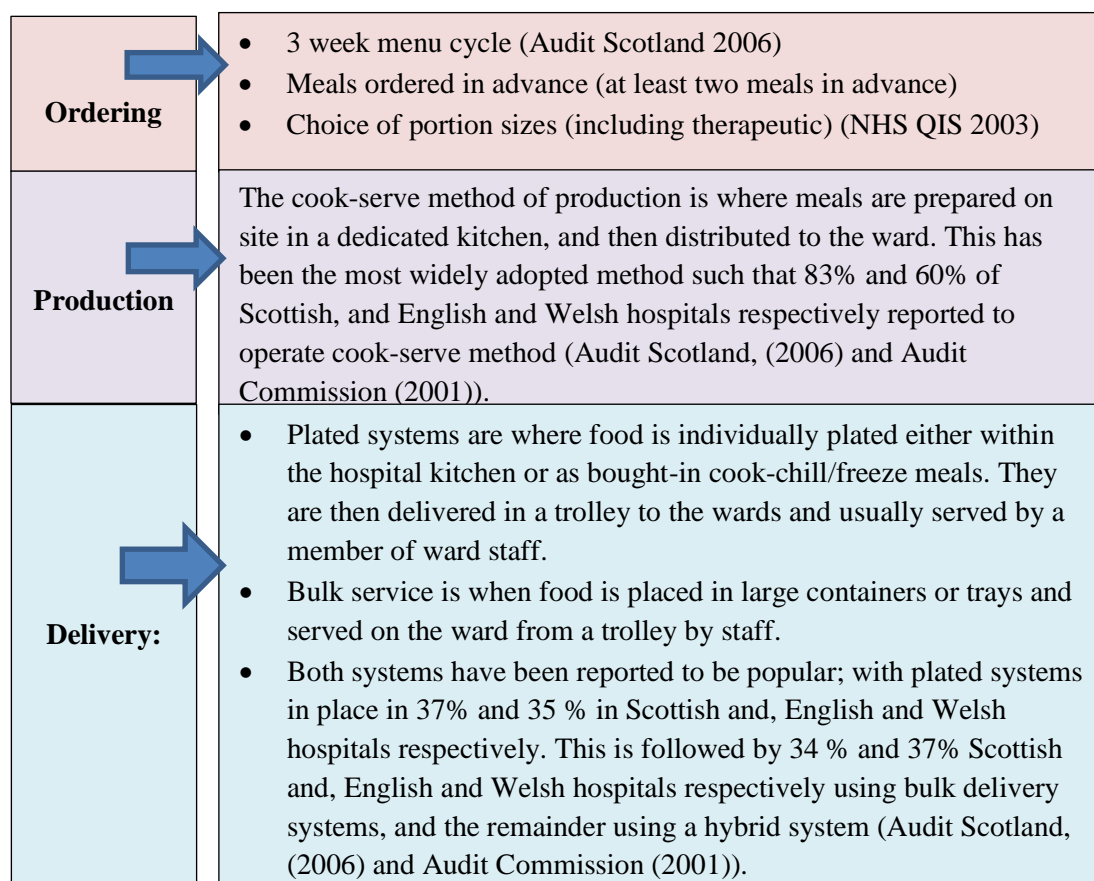


Figure 1.1: Overview of meal provision services in hospitals

Acute hospitals (93 % in Scotland) with long-stay beds operate at least a three week menu cycle to maintain variety in the meal options for these patients (Audit Scotland 2006). Some catering services also are using flexible approaches which allow patients to order their food nearer to meal times. However, 63% of Scottish hospitals require patients to order meals at least two meals in advance (Audit Scotland 2006).

Policies relating to food provision in hospitals state that patients are given a choice for all food and drink options, including therapeutic and TMD (Scottish Government 2008; Welsh Government, 2010). There is also to be a choice of portion size for all main courses (NHS QIS 2003). An audit of catering systems in Wales revealed that most hospitals visited had menus that provided patients with an appropriate choice of

food (Wales Audit Office 2011). In Scotland, 97 % of hospitals were found to offer at least a choice of two main meals from the lunch and dinner menus (Audit Scotland 2006). It is however not clear if this is true of TMD meals (not individually reported). It is not unreasonable to assume that as these diets are limited by their texture requirements, that less choice is available.

As seen in Figure 1.1, methods of food production in hospitals vary to include; cook-chill/cook-freeze, cook-serve, or a hybrid method including a combination of both the aforementioned methods. Interestingly, the Audit Commission (2001) assessing hospital catering in England and Wales reported that costs varied depending on the method of production. For example, the average spending on food and beverages per patient when meals were produced on site was £2.25 compared to meals bought in from a commercial supplier which costed £3.70 for cook-chill/freeze meals (Audit Commission 2001).

The fact that the cook-serve production method appears to be most affordable method, it is likely that this is still the dominant production technique in place in hospitals today which continue to operate within tight budget constraints. However there are no recent data available to support this. If it is the case that catering services use on-site production methods, this suggests that hospital sites have the potential to develop new recipes in line with requirements and preferences of their patient population. In other words, hospitals can set individual goals that are based on pre-approved menu planning standards (for example ‘Food in Hospitals’ (Scottish Government 2008) and the ‘All Wales nutrition and catering standards for food and fluid for hospital inpatients’ (Welsh Government 2010) menu planning guidance).

Delivery systems to the ward may be by bulk systems, plated systems or a hybrid (mix of plated and bulk service) (Figure 1.1). A study conducted in Bournemouth specifically sought to assess patients' (n=180) preference between the plated and bulk system. Results showed that the bulk method of food distribution enabled all foods to have a more acceptable texture, and for some foods more acceptable temperature (potato, $p = 0.007$; poached fish, $p = 0.001$; and minced beef, $p \leq 0.0005$). Other foods were also reported to have more acceptable flavour (broccoli, $p \leq 0.0005$; carrots, $p \leq 0.0005$; and poached fish, $p = 0.001$) using bulk service compared to plated service delivery (Hartwell et al. 2007). However the plated delivery system offers benefits in terms of meal portioning, allowing greater control over the provision of nutrients.

Plated delivery also allows kitchen staff to present the meal in an attractive manner on the plate (Pedersen and Overson 2000). There is however evidence that there may be greater plate waste with a plated meal service compared to a bulk service. In fact in a study carried out by Wilson et al. (2000) it was demonstrated that in 108 patients (51 plated service, 57 bulk service) food intakes were greater (expressed as a percentage of the meal served) with the bulk service (85.5% consumed of served) compared to the plated service (66.5% consumed of served). However another study in a Scottish rehabilitation centre for older adults (n= 47) demonstrated a strong correlation ($r=0.84$, $p<0.001$) between energy provision and consumption over 24 hours, using a plated service (Ofstad et al. 2013). This suggests that food consumption increases with increased food provision. It should be considered that using the bulk system, problems with loss of appetite by individuals may be more

easily overlooked, as it more difficult to estimate individual consumption determined by plate waste methods.

1.3.3 Challenges encountered with food provision services in hospitals

As malnutrition remains a problem (BAPEN 2012a), it appears that strategies currently in place do not appropriately manage the condition. Further it has been identified that often patients become further malnourished during their stay at hospital (McWhirter and Pennington 1994; Pichard et al. 2004). Despite substantial efforts to adequately provide sufficient meal provision services, these have been identified as a potential cause for poor intakes. It appears that whilst progress has been made to ensure adequate provision, patients' nutritional care is not yet being prioritised at ward level (Audit Scotland 2006). Audits evaluating food provision services in hospitals report results which vary by region, data collection methods, and by who conducted the audit. A summary of the main audits assessing patient satisfaction can be seen in Table 1.8. Specific potential factors attributing to the persisting problem of malnutrition in hospitals include; the difficulty meeting individual needs, reduced nutrient consumption due to disease, food wastage or provision of diets with reduced nutritional profiles (e.g. a TMD), difficulty with eating, and inadequate meal provisions outside normal catering hours.

Table 1.8 Overview of patient satisfaction of hospital food provision services

Region	Audit (s)	Main findings and recommendations regarding patient satisfaction
England	Acute Hospital: Catering (Audit Commission 2001)	The average score on food quality and meal service was 7.6/ 10. However, more than a third of trusts do not meet these targets (DOH 1996)
	CQC inpatient Survey (Imperial College Healthcare NHS Trust, 2012).	Quality of food rated: 5.3/10. Choice of food rated, 8.4/10 Assistance with eating rated as 6.5/10.
Wales	Acute Hospital: Catering (Audit Commission 2001)	The average score on food quality and meal service was 7.6/ 10 (DOH 1996)
	Hospital catering and Patient Nutrition (Wales Audit Office 2011)	Most hospitals provide an appropriate choice of meals and patients are generally satisfied with the food they receive, but the nutritional assessment of menus and patients' mealtime experiences need to improve
Scotland	Catering for Patients (Audit Scotland 2003;2006)	Catering services are offering patients more choice however more is needed to be done to ensure patients' nutritional care.
	NHS Scotland National Catering Half Yearly Report (2012)	Nutritional needs of population, menu planning and, therapeutic diet provision continue to be the most challenging categories, but are steadily improving
Northern Ireland	Catering services in Northern Ireland (Department of Health, Social Services and Public Safety 2001)	The average score on food quality and service for the eleven departments who completed the satisfaction survey is 8.0.
	Food for thought (Patient and Client Council 2011)	Patients are generally happy with the quality of food. However, more care and attention is needed regarding portion size, special dietary needs, protected meal times, assistance with eating and communication between patients and staff.
Other	Hungry to be heard (Age UK 2006)	People in later life share their frustrations about not getting the food or the help they need at mealtimes.
	Still Hungry to be heard (Age UK 2010)	Lack of consistency in quality across hospitals on mealtime services. Generally insufficient help at meal times

Due to the diversity of the populations in hospital (and care home) settings in terms of activity levels, ethnicity and disease state; the nutritional content of normal hospital diets may not meet individual requirements. Although considerable work has

been undertaken to address these specific factors, meeting the nutritional needs of the hospital population remains a challenge with reports stating that 10-30% of boards in some regions are still not complying with nutritional guidelines (Health Facilities Scotland 2012).

As outlined in the NHS investment plan (Department of Health 2001a) (section 1.3.1, Table 1.7), food is supposed to be available to patients 24 hours a day and there should be snacks on wards as well as vending machines accessible to patients (NHS Plan 2000; Scottish Government 2008). An audit of NHS hospitals in Wales revealed that whilst most hospitals have arrangements in place to provide snacks and several have implemented snack menus, three-fifths of respondents (patients) reported that snacks were rarely or never available (Wales Audit Office 2011). This is likely to impact on overall energy intakes, since it has been demonstrated in a study conducted in an orthopaedic rehabilitation hospital in Scotland (n= 58) that more than 90% of snacks provided were consumed. Further investigation revealed that these food items provided almost one quarter (23%) of total energy intakes (mean (SEM) energy intakes; 310 (26) kcal) which was in fact comparable to the contribution from breakfast (316 (18) kcal, 23.4 % of total energy consumption) and lunch (380 (26) kcal, 28.2% of total energy consumption) and dinner (350 (17) kcal, 25.9% of total energy consumption) (Williams et al. 2011).

Another factor contributing to inadequate intakes is the disruption of patients during mealtimes for routine tasks such as consults, tests, and visits from family members during meal provision times. To combat this, the introduction of a protected mealtime initiative (PMI) is advised (NPSA 2007; 2009). These are periods of time on a hospital ward when all non-urgent activity stops, allowing the patient to eat

without being interrupted. It is also advocated that during these times staff are available to provide assistance with feeding (NPSA 2009). Whilst this initiative has the potential to reduce the risk of missed meals if implemented and maintained correctly, a recent review has discovered wide discrepancies in its effectiveness throughout NHS hospitals in Scotland (Audit Scotland 2006) England and Wales (NPSA 2007). Findings from Audit Scotland (2006) have also reported wide discrepancies in the implementation of the initiative; in fact less than ¼ of hospitals report to operate protected mealtime policies (Audit Scotland 2006).

Despite the implementation of PMI, energy intakes do not necessarily improve. An audit conducted (Charing Cross Hospital and Hammersmith Hospital, London) evaluating the effectiveness of the initiative on energy intakes found a small (60 kcal) but not significant increase in energy intakes at lunch (260 versus 200 kcal, $p = 0.25$) and a decrease (6.5 g) in protein intake (14.0 versus 7.5 g, $p = 0.04$) after the introduction of protected mealtimes (PM) (Hickson et al. 2011). There was however a considerable time frame between the baseline measurements before PM (June/July 2008) and after PM were introduced (October/November 2009), likely reflecting a different patient group with different conditions and resulting appetites, and different menus (although similar quantities of energy and protein were provided at each occasion), all potentially contributing to the overall eating experience and also impacting on intakes.

No studies have specifically investigated the effectiveness of a PMI for improving intakes in those who require a TMD. However, these may potentially benefit this group as they may require additional assistance with eating (as provided within the PMI) due to reduced motor control. For example, reduced motor control (and in

some cases cognitive impairment) is observed in patients with dementia (Groher and Crary 2009), and in patients who have suffered from a stroke (Krug and McCormack 2009) as well as those diagnosed with neurodegenerative conditions, all of which may lead to prescription of a TMD (section 1.1).

Regardless of the overall quality and nutritional content of the meals served, if patients cannot physically consume their meals, adequate intakes cannot be met and malnutrition will persist. In general, it is advised that assistance with eating meals be available (NHS QIS 2003, standard 3), however in 2006, a Healthcare Commission survey found that fewer than 58% of the patients who required help eating their meal, actually received it (Healthcare Commission 2006). Assistance with eating was also flagged as an area for improvement in Wales (Wales Audit 2011) and Northern Ireland (Patient and Client Council 2011).

Whilst this strategy may add to the cost of food provision, this may be cost effective if patient energy needs are met thus reducing malnutrition risk. One study conducted in Australia in older adult hospital inpatients (n=23, mean (SD) age 83.2 (8.9) years) evaluating the presence of volunteers to help at meal occasions, demonstrated significant increases in lunchtime energy (396 kJ/ 94 kcal) and protein intakes (4.3 g) (Manning et al. 2012). These, in combination with additional strategies to improve energy intakes, may result in clinically significant intakes also. It should also be considered that a number of Trusts have introduced trained volunteer schemes (e.g. “feeding buddies” (NHS Southend, NHS Basildon, NHS, Airedale, NHS Bradford, to name a few) to assist and support patients during mealtimes. In these cases, patients have an increased opportunity to improve their intakes for no additional cost.

The level of food wastage in hospitals is also reported to be high (Barton 2000). It should be considered that hospital surveys reviewing meal waste often only count 'unserved meals' because of the practical difficulties in measuring wastage left on the plate after patients have eaten (plate waste). In fact, it is advised that patient's individual intakes be assessed (NHS QIS 2003 (standard 3); Department of Health Social Services and Public Safety 2010a; The Nursing Care Standards for Patient Food in Hospital (standard 4)). However, due to time competing tasks to be carried out on the wards, this is not always carried out universally (Department of Health, Social Services and Public Safety 2001) or is adequately documented (Wales Audit Office 2011). A recent study conducted in two adult acute wards in Scotland (n=27 patients (n=12 ward A: n=15 ward B)) evaluated the relative validity of food record charts (FRC's) in relation to the weighed plate wastage method (Bartkowiak et al. 2013). This study revealed most of the FRCs were incomplete (100% FRCs ward A and 87% ward B) and food items were often misclassified leading to further discrepancies between the two recording methods. This demonstrates that more work is needed to establish feasible and reliable food intake recording methods at ward level.

Providing adequate nutrition for those with special dietary requirements can also present challenges thus increasing the risk of poor dietary intakes. For example, the preparation of TMDs which may be offered within the management of dysphagia (section 1.4) can have reduced energy and nutrient density as a result of the addition of low or non-caloric fluids during their preparation (SIGN 119 2101; Vigano et al. 2011; BDA 2012a). Latest results from the NHS Scotland National Catering Half Yearly Report demonstrate that whilst therapeutic diet provision is steadily

improving, it still remains an issue with 70-90% of boards in some regions complying with guidelines (Health Facilities Scotland, 2012) highlighting the need for continued improvement.

Further to this however is the added difficulty of providing snacks for those with special dietary needs. A study conducted by Bannerman and McDermott (2011) investigating food intakes with a TMD reported that snacks provided significantly less energy in those requiring a TMD (173 ± 110 kcal) compared to a standard diet (343 ± 147 kcal, $p=0.001$). Rather alarmingly within the provision of snacks to those requiring a TMD, none matched the requirements of their TMD prescription. This highlights the need for further development of suitable foods for provision within a TMD, which is already a diet with limited food choices.

1.4 Nutritional management of dysphagia

For those with dysphagia who tolerate oral nutrition, diet modifications and compensatory techniques are advised. As modified diets (TMD) are the foundation of dysphagia management (when oral nutrition is tolerated) and food based strategies are of particular interest in this study, these will be discussed in extensive detail in the subsequent section (section 1.4.1). Compensatory techniques refer to postures (the manipulation of head or body posture) or manoeuvres (the manipulation of the swallowing mechanism). These may also be advised alongside therapy techniques including exercises or strategies designed to facilitate or stimulate the swallow, with

the main objective being to influence the speed and directional flow of the bolus (Sura et al. 2012).

Ultimately the decision surrounding the nutritional care of each patient should be made by the multidisciplinary team in consultation with the patient and their carers/family (NICE 2006). Guidelines do however state that in the acute setting people unable to swallow safely or take sufficient energy and nutrients orally should have an initial two to four week trial of nasogastric enteral tube feeding (NICE 2006). This advice aligns with findings from the FOOD trial which demonstrated that compared to avoidance of tube feeding, early tube feeding was associated with an absolute but non-significant reduction in risk of death by 5.8% (95% C.I: -0.8 to 12.5, $p=0.09$ (Dennis et al. 2005). However a recent review (Geeganage et al. 2012) which evaluated the interventions for dysphagia and nutritional support in sub-acute stroke concluded that there was no difference for death (OR 0.94; 95% C.I: 0.68 to 1.31) or dependency (OR 1.12; 95% C.I: 0.81 to 1.56) with early feeding (defined as within seven days of stroke onset) as compared to late feeding. Regardless of the route and timing of delivery of the enteral nutrition tube feeding should be stopped when the patient has established adequate oral intake (NICE, 2006). This aligns to the food first approach, whereby oral nutrition, via food is the first choice for managing nutritional intake.

1.4.1 Texture modified diets (TMD)

As mentioned earlier (section 1.1.2 and 1.3.1), TMDs are frequently prescribed for the nutritional management of dysphagia. These are rarely a diet of choice, but a diet

of necessity if an individual is to maintain their nutritional needs orally (Atherton et al. 2007).

These diets are prescribed globally for the nutritional management of dysphagia in order to promote a safer swallow by avoiding the risk of aspiration. They aim to, maximise health and well-being (Burton et al. 2011), minimise the risk of under-nutrition and dehydration (Finestone et al. 2001) minimise risk of aspiration pneumonia (Perry and Love 2001) and maintain oral nutrition (Burton et al. 2011). It should be re-iterated that TMD are not only prescribed for those who are suffering from dysphagia, but those also with mastication difficulties, or for those with dentures. This alludes that a high number of older adults likely require some type of texture modified diet. In care facilities it is advised that at least two different textures of meals are offered (BDA 2012a).

Before discussing these diets, it should be recognised that the terms used to describe these diets vary worldwide as highlighted in a review by Penman and Thompson, (1998). Despite the fact that this review was conducted nearly 15 years ago, variations in the terms still exist (National Dysphagia Diet, ADA 2002; Dietitians Association of Australia and the Speech Pathology Association of Australia Limited, 2007; Irish Association of Speech and Language Therapists (IASLT) and the Irish Nutrition and Dietetic Institute (INDI) 2009; BDA 2012a). For a successful therapeutic outcome however, it is necessary that everyone involved in the management of the patient, use the same terminology while recommending a TMD. The most widely used therapeutic diets for dysphagia and/or mastication difficulties are a series of graded consistencies, such as liquidised/thin puree, thick puree/soft

and smooth, soft/finely minced and minced/normal. However, none of the definitions have been based on objective measurements.

The International Dysphagia Diet Standardisation Initiative (IDDSI) is currently in place which aims to develop global terminology and definitions for texture modified foods and thickened liquids for individuals with dysphagia, of all ages, in all care settings and all cultures. At present this project is at an early stage. Whilst there has been an attempt to quantitatively define acceptable ranges of viscosity for stages of liquids within the American guidelines issued for the dysphagia diet (American Dysphagia Diet, 2002) no such measurements have been issued for foods. Few experimental studies have attempted to quantify the textures of different TMD categories (Wendin et al. 2010; Tahiro et al. 2010) and some information regarding particle size of foods within different categories also exist (Cichero et al. 2013). However due to differences in defined textural categories and subjective terminology used, it is difficult to fully translate these across all foods. These may however provide a reference range of textures to which a particular texture category could belong.

1.4.2 TMDs for facilitating intakes:

As well as the lack of studies available which demonstrate food based strategies to be effective for improving outcomes in the management of malnutrition, there are very few studies evaluating the effectiveness of texture modified diets, for improving energy intakes. In fact, just two RCTs (Germain et al. 2006; Taylor and Barr 2006)

and one cohort study (Foley et al. 2006) were found which consider energy intake as an outcome measure.

Only one of the studies directly compared the use of a pureed diet compared to other methods of provision (Foley et al. 2006). In this study it was demonstrated that energy intakes were greatest with enteral nutrition at day 7 (+ 5 kcal/kg/day), day 14 (+ 5.6 kcal/kg/day), day 11(+ 4 kcal/kg/day) and day 21 (+ 8.4 kcal/kg/day). It should be highlighted however that on most days, intakes exceeded requirements with enteral nutrition, for example on the day with the biggest difference in energy intakes between the two methods (day 21), enteral nutrition provided 23.3% more energy than required. It should also be considered that energy intake is just one outcome measure, and other factors such as QOL should also be factored into the decision (made in consultation with patients and/or carers) surrounding nutritional care. Also it should be highlighted that even with TMD, at least 75.7% (+/- 24.2%) of energy requirements were met with the dysphagia diet (ranging from 75.7% (+/- 24.2%) to 94% (+/- 18.0%) over the 3 week investigation period. Intakes could perhaps be increased further using additional strategies (discussed section 1.4.4) alongside the provision of a TMD.

Aside from the possible increase in energy intakes (Germain et al. 2006), TMD have been positively found to reduce aspiration (Logemann et al. 2008; Diniz et al. 2009). The study by Diniz et al. (2009), demonstrated that 39.3 % of participants (n=61) aspirated on water compared to 4.9% of participants who aspirated on spoon-thick consistency (in a randomised crossover design). Similarly, Logemann et al. (2008) demonstrated that fewer participants aspirated a honey thickened fluid, compared to

a thin fluid with the chin down postural adjustment (53% compared to 63 % respectively, $p=0.001$).

It is hypothesised that providing nutrition orally can help to rebuild the strength of the muscles (and avoid further muscular atrophy) involved in the swallowing process thus, speeding recovering. Robbins et al. (2007) stated that restoration of swallowing function (after stroke) may partly depend, on the muscle strength. Testing this they conducted a study evaluating the effect of lingual exercise programme on swallowing recovery. They demonstrated that after an eight week programme of exercises (isometric lingual exercise program by compressing an air-filled bulb between the tongue and the hard palate) lingual strength was improved in stroke patients with dysphagia. Further, they demonstrated that these same individuals developed greater lingual strength during swallowing naturally, as shown by higher swallowing pressures (Robbins et al. 2007).

Clearly more studies need to be conducted to demonstrate the effectiveness of TMD for facilitating food and energy intakes. It is difficult however to design a well-controlled RCT as it would be unethical to provide an individual with dysphagia with a diet that differed from their prescription. Since controlled studies are needed in order to build a foundation for the evidence base, research should initially be conducted in a healthy group (Stubbs and Elia 2001). After sufficient evidence exists supporting the strategies in well controlled studies, similar interventions could be trialled in clinical settings, using cohort designs (where necessary) in order to prioritise patients' care.

1.4.3 British National Guidelines for TMDs

Within the UK, The Royal College of Speech and Language Therapists (RCSLT) and The British Dietetic Association (BDA) produced “*The National Descriptors for Texture Modification in Adults*” in 2002. These were then updated (to improve clarity by reducing the number of diet categories from five categories to four categories) and re issued in 2012. As already mentioned, the guidelines in the UK for the provision of a TMD differ to those elsewhere (National Dysphagia Diet, ADA 2002; Dietitians Association of Australia and the Speech Pathology Association of Australia Limited, 2007; Irish Association of Speech and Language Therapists (IASLT) and the Irish Nutrition and Dietetic Institute (INDI) 2009).

The aim of the UK National Descriptors is to categorise foods and fluids based on different textures to allow care givers to produce meals of appropriate consistencies across patients. For thickened fluids, stages 1-3 are used, with stage 1 having the lowest viscosity and stage 3 being the most viscous. Foods are categorised into Textures B-E (BDA 2012a) with “Texture B” described as having a “smooth, pouring, uniform consistency” and “Texture E” including foods that consist of “soft, moist food”. An important observation however, is that while the document gives examples of different consistencies, there are no standard measurements for viscosity issued thus these subjective descriptors are somewhat open to interpretation.

In theory, as the patient’s swallowing ability improves, the diet can be altered so that the patient can tolerate more varied textures. A majority of patients with dysphagia typically recover their swallowing function within the first month after a stroke, but as many as 40% of stroke patients continue to experience dysphagia one year after

the initial incident (Corrigan et al. 2011). Thus these individuals will be restricted in their dietary intake by the fact that they will require a TMD for a long period of time potentially negatively impacting on nutritional status, unless adequate food/nutrient intakes are met. Individuals experiencing dysphagia as a consequence of neurodegenerative conditions (for example, MND, MS, Parkinson's or Alzheimer's disease) are unlikely to experience improvements in their swallow function. In fact, for many swallow function may further deteriorate to the point that nutrition will not eventually be tolerated via the oral route, thus that other methods are warranted (Royal College of Physicians 2010).

Aside from wide variations in the standards surrounding the terminology for a TMD (National Dysphagia Diet, ADA 2002; Dietitians Association of Australia and the Speech Pathology Association of Australia Limited, 2007; Irish Association of Speech and Language Therapists (IASLT) and the Irish Nutrition and Dietetic Institute (INDI) 2009; BDA 2012a), which certainly adds confusion when designing diets for individuals with mastication and swallowing disorders, there are also discrepancies in the preparation of meals to meet these guidelines.

A study carried out by Steele et al. (2003) explored the relationship between objective rheological measurement and clinician's subjective impressions of the consistency of different thickened liquids in order to explore the level of inter individual variability in perceived consistencies and hence TMD preparation. In this study, fifty speech and language therapists (SLT) were asked to rank ten common liquids in order of increasing viscosity. The results showed good correlations for liquids at the ends of the spectrum however there were large variations for the liquids

in between. These findings suggest that we cannot rely on visualisation or stirring to give an accurate idea of fluid viscosity, although currently this is how products are often prepared in practice. Whilst this finding was demonstrated in fluids it is possible that these inconsistencies also exist when preparing foods to various textures. Ensuring the correct texture of food is clinically important in the management of patients with dysphagia, because it can influence the likelihood of aspiration and retention in the pharynx after swallowing.

Rosenvinge and Starke (2005) demonstrated that providing recommendations for hospital staff resulted in higher compliance to speech and language therapist (SLT) advice for management of dysphagic patients. The overall level of compliance with the recommendations of SLTs regarding consistency of fluids, dietary modifications, amount to be given at a single meal/drink, swallowing strategies, general safe swallowing recommendations and whether supervision was required, observed at an acute and general hospital in the UK was 51.9% (95% C.I 46.8-57.1). This was before a tailored intervention (which included the development of a dysphagia compliance group, appointment of dysphagia/nutrition link nurses, targeted training courses for nurses, health care assistants and catering staff, pre-thickened drinks available on the wards and the implementation of a new, clearer swallow advice sheet). The level of overall compliance to SLT recommendation increased significantly after the intervention to 73.3 % (95% C.I 67.8-78.8.). An important finding was that the most common reason for non-compliance with recommendations in the first audit was due to thickening fluids to an inappropriate consistency by staff. It was noted that overall compliance to the advice regarding food consistencies was good at the first audit (82.5 %, 95% C.I 72.6-92.3 %) and remained to be good at the

second audit (78.7%, 95% C.I 68.4-89.0%. There was however large variation in the level of compliance which further highlights the need to standardise the methods to which thickened fluids and foods are prepared in practice.

Unfortunately the practicality of running quantitative analysis on meals prepared in hospitals and care homes to ensure viscosities are standardised and match the relevant guidelines is questionable. Food texture and viscosity are typically measured using specialist equipment and it is unlikely that these measurements could be taken for the large range of texture modified meals that may be offered in clinical practice. Standard laboratory measurements of viscosity normally use a viscometer at a controlled temperature and shear rate. However, although viscometers accurately measure viscosity, they are expensive and not always available (Paik et al. 2004).

Even this method of viscosity assessment, whilst giving a quantitative measurement of the food being tested, will not truly be representative of what may occur during ingestion. Initial digestion of carbohydrates and fats due to amylase and lipase present in saliva, as well as the additional fluid from saliva, and temperature changes incurred in the oral cavity will likely alter the texture of the food even before the swallow is initiated. The length of time foods spend in the oral cavity will likely vary also, depending on the severity of the individuals swallowing disorder and mastication ability, therefore causing various levels of physical changes to the food. Also, as foods are typically described as “shear thinning” (the viscosity will change depending on the shear applied), the food may undergo further textural changes depending on the shear that is induced during transit through the pharynx and

oesophagus. As viscosity measurements are taken at a constant shear rate, this may not truly represent the phases incurred during the swallowing process.

There is also likely to be a large variation in individual's swallow, resulting in large variations in the shear applied to these foods. Nicosia and Robbins, (2001) also suggested that variations in tongue pressure generated among dysphagic populations may differ thereby affecting the resulting bolus flow. Therefore there will be huge variation between how thickened foods and liquids will behave, depending on the generated tongue pressure. Despite these limitations, it is useful to categorise TMD meals in order to identify their suitability for patients. One method has been proposed to quickly assess different viscosities using a line spread test (LST) (Paik et al. 2004). It was found that logarithmic viscosity (cP) values measured using a viscometer were inversely correlated with the extent of spread (cm) on a LST ($r = -0.95, p < 0.0001$). Strategies like this to quickly measure foods viscosities may prove beneficial ensuring correct textures are being prepared, however will not avoid any changes in viscosity that ensue over time or with temperature changes which may occur during transit from the meal preparation area to the patient, or the potential textural changes that may occur during ingestion.

Another strategy to overcome the difficulty and practicality of taking quantitative measurements of food prepared to particular textures, within food provision services, could include the prior development of standard recipes and protocol to ensure final viscosities (if prepared following a strict protocol) are in line with the desired texture recommendation. Wendin et al. (2010) further suggest that both objective (sensory analysis on food attributes, including chewing resistance, ease of swallow,

homogeneity as well as properties of melting, wobbling, creaminess, firmness, graininess, and porosity) and quantitative (rheological) measurements are needed to correctly categorise foods of different textures to be provided to those who are prescribed a TMD.

It is clear from the studies discussed so far that food provision for those requiring a TMD presents challenges (Table 1.9). Despite this it is crucial for consumers' safety that this is done and complied with universally. Maintaining adequate nutrition in these patients is both a clinical issue and a catering concern. It should be highlighted here that the guidelines (in the UK) do not mention the potential of thickened foods and fluids becoming nutritionally dilute nor do they offer any guidance on possible food enrichment or fortification. However it has been noted that there is insufficient evidence regarding food enrichment in the dietary management of dysphagia (SIGN 119 2010) and needs to be investigated further. The reported difficulties with food provision for those requiring a TMD does not however provide sufficient rationale to revoke food based approaches as a nutritional management strategy.

Patient safety must be the primary concern when considering the best method to meet nutritional requirements. The NHS has demonstrated its commitment to ensuring patient safety by the setup of the NPSA (now transferred to the NHS Commissioning Board Special Health Authority). Consumption of meals that do not meet required textural standards can result in aspiration potentially leading to aspiration pneumonia, or to poor food intakes contributing to malnutrition (section 1.1.2). Similarly, production of meals that do not fulfil nutritional requirements further

contribute to poor intakes and malnutrition. Thus, development and production of these therapeutic meals (*i.e.* TMD) that are “fit for purpose” so that they safely facilitate adequate intakes falls within this goal of ensuring patient safety.

Table 1.9: Challenges with food provision for those requiring TMDs

Issue	Relevant guidelines and/or standards	Relevant research
Due to swallowing difficulties, the food intake of patients with dysphagia can be compromised	TMD and compensatory techniques Where oral feeding not possible enteral nutrition, trialling NG first (NICE 2006; SIGN 119 2010) followed by PEG.	Lack of studies evaluating TMD and compensatory techniques on intakes. However, can reduce aspiration (Logemann et al. 2008; Diniz et al. 2009).
The nutrient content is often poor, due to dilution with fluid, often water, to obtain the right consistency	It is advised that these be enriched, although generally agreed that there is a lack of evidence to support this (SIGN 119 2010).	Nutritional content reduced (Vigano et al. 2011) Evidence that enrichment may promote intakes in standard diets (Gall et al. 1998; Odlund Olin et al. (1996 ;2003). No strong evidence clearly demonstrating the effectiveness in TMD. Although enrichment with micronutrients has resulted in greater intakes (Adolphe et al. 2009).
Standard provision tends to be a purée of a suitable menu choice	TMD provision defined by BDA descriptors (BDA, 2012a) which can limit food choice	Germain et al. (2006) demonstrated improved energy intakes with a new dysphagia diet menu.
Puréed meals are often not well received by patients	Food, including therapeutic meals should be appetising (NHS QIS 2003; SIGN 2010)	Cassens et al. (1996) demonstrated greater intakes with improved aesthetics of TMD.
It is difficult to maintain a consistent and appropriate consistency and, therefore, safe swallowing	In the UK TMD provision defined by BDA descriptors (BDA, 2012a). These are subjective (<i>i.e.</i> lacking quantitative descriptions) and inconsistent worldwide.	IDDS working on standard global terminology (Cichero et al. 2013). Others are working toward standardising dysphagia diets using quantitative methods (Wendin et al. 2010; Tahiro et al. 2010).

1.4.4 More food based strategies to improve intakes of those requiring a TMD

Since malnutrition is frequently associated with dysphagia, similar strategies (as discussed in section 1.2.1) to improve food and energy intakes as for malnourished patients may be adopted in the nutritional management of dysphagia. These need to also consider textural prescriptions and elimination of certain high risk foods, therefore strategies such as increased variety and altered meal patterns which also follow the guidelines for TMD (BDA 2012a) have potential for improving intakes.

It has already been discussed that improving food choice by offering greater variety leads to improved intakes in healthy subjects (Norton et al. 2006a). Therefore this could also have clinical application for those prescribed a TMD. Germain et al. (2006) demonstrated significant increases in energy intake when a group of patients with dysphagia were offered a novel dysphagia diet for 12 weeks compared to a control group who received their same usual diet on rotation. Daily increases of 563 ± 429 kcal were observed from baseline to 6 weeks, and increases of 611 ± 408 kcal from baseline to 12 weeks in the intervention group. The control group's daily energy intake did increase, but indeed to a smaller extent (81 ± 169 kcal from baseline to 12 weeks) than that observed in the intervention group. It should be recognised that there is huge variation in mean intakes therefore these findings may not be as clear when investigated on an individual level and may in fact be related to individual taste preferences and/or disease state of the individuals studied. It is however advocated in the management of stroke patients, that patients should have a choice of texture modified dishes (NHS QIS 2003; SIGN 119 2010).

Despite the suggestion that the provision of smaller, more frequent meals may improve energy intakes in dysphagic individuals (Layne 1990), it seems that this strategy does not necessarily prove to be successful (Taylor and Barr 2006). The study by Taylor and Barr demonstrated that energy intakes did not differ in a randomised crossover design when participants were provided with the same total daily energy (from the same texture modified foods) over either three meal occasions or five meals occasions. Fluid intakes (from beverages) however were increased with the increased frequency of meals (698 ± 156 ml (5 meals) versus 612 ± 176 ml (3 meals)) by 86 ml. Although this is quite low representing $< 6\%$ recommended daily fluid provision of ≥ 1.5 litres fluid/day (Scottish Government 2008), it is promising, particularly as individuals with dysphagia are at risk of poor hydration status due to the difficulty to consume enough fluid (Leibovitz et al 2007; Bannerman and McDermott 2011), and also the added risk of water binding as encountered with the use of gum based thickeners resulting in the poor absorption of water (Kemp 2001).

More studies need to be conducted, trialling various altered meal patterns which complement other food based strategies, such as the strategy that is the focus of the current thesis; energy enrichment. An energy dense diet may be provided to those requiring a TMD to overcome energy and nutrient dilution and help with the nutritional management of their condition. The effectiveness of providing energy dense texture modified diets for improving energy intakes however needs to be evaluated, as there is insufficient evidence supporting this strategy using TMD (SIGN 119 2010). It should be reiterated that the lack of evidence is due to the apparent bias in the literature with many researchers focussing on the nutritional benefit of supplementation with artificial nutrition rather than food based strategies.

In fact, no RCT's specifically evaluating increasing the energy intakes of TMD meals exist.

In summary; as the gastrointestinal route remains the most physiologically appropriate way of providing nutritional support, ideally when tolerated, oral nutrition is preferred. In dysphagic individuals delivery of nutrition via the oral phase may in fact contribute to improved bolus control and swallow function (Robbins et al. 2007). It is acknowledged that food based strategies for the nutritional management of dysphagia (*i.e.* TMD) may present challenges for catering providers. These challenges alone do not support the use of artificial nutrition when oral nutrition is tolerated but rather offer the opportunity to develop and improve existing food provision services.

There is considerable scope for additional research leading to the development of appropriate food based strategies to successfully improve intakes of these therapeutic diets. For those consuming TMD who have reduced food and thus energy intakes, enrichment of these meals may aid in meeting adequate intakes. This however has not been assessed specifically in meals that match the textural categories advocated for dysphagia management. For this strategy of enrichment of TMDs to be successful, considerations must be made into the impact of the meals alterations on appetite and eating behaviour. Thus specific investigation into the impact these meals have on eating behaviour using a controlled study design is warranted.

1.5 An overview of the regulation of food intake

It is unclear if the observed reduction in food intakes with TMD (Wright et al. 2005; and Bannerman and McDermott 2009) is a result of disease state accompanying the dietary prescription, to the aesthetics of the meal, the impact of the alterations (e.g. texture, nutrient density) on appetite, or a combination of these. However a study conducted by Ekberg et al. (2002) reported that 50% of dysphagia sufferers consumed less food than before their diagnosis, despite the fact that one third of these patients still felt hungry or thirsty after meals. This suggests that intakes were reduced for reasons other than disruption in appetite pathways associated with disease state, as hunger was still reported despite apparent satiation.

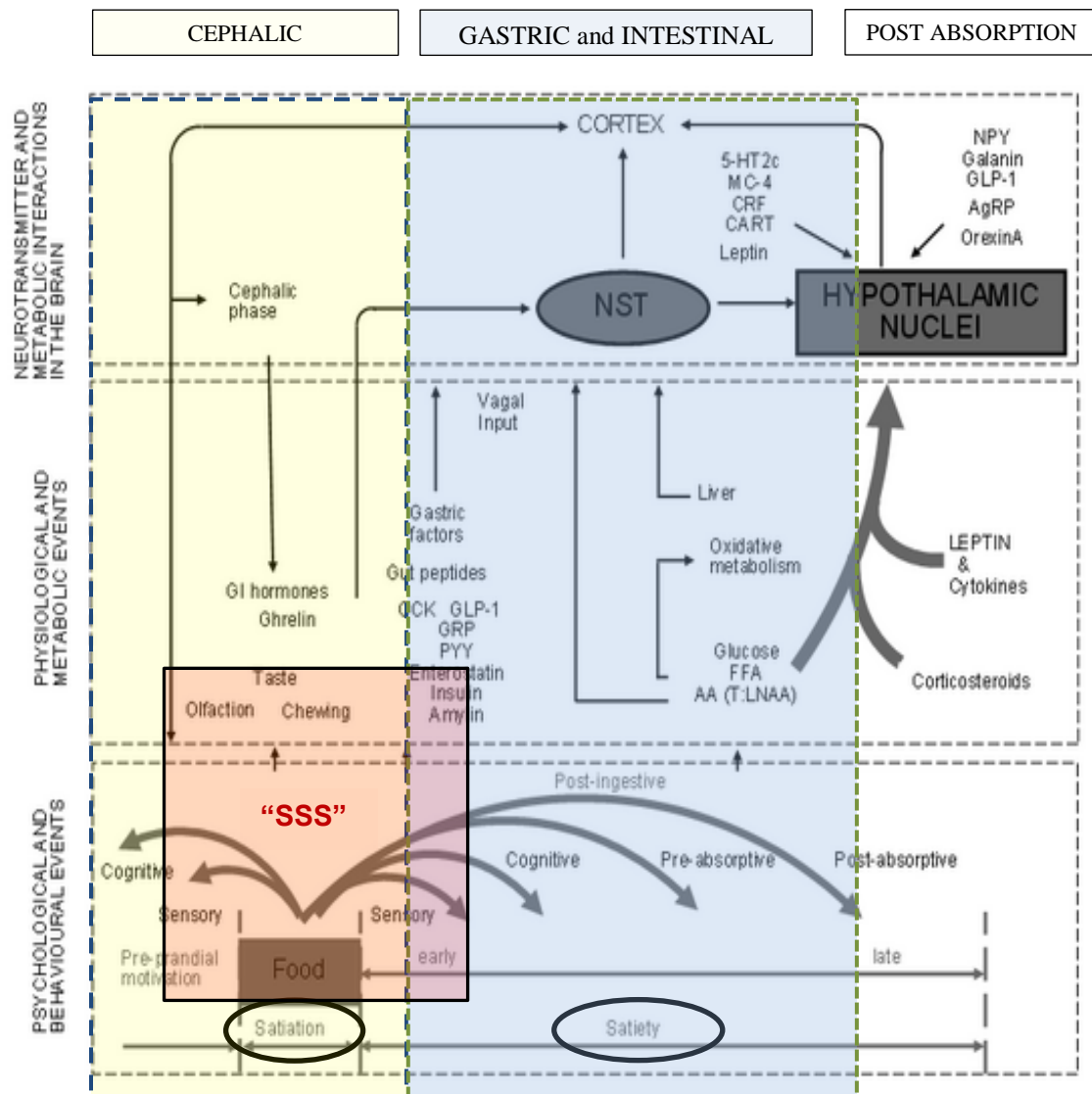
Food based strategies using standard texture meals have demonstrated to have the potential to improve energy intakes, such as enrichment (Gall et al. 1998; Odlund Olin et al. 1996 ;2003; Silver et al. 2008) and increased variety (Norton et al. 2006a; Henry and Hollis 2007), and these may have similar potential in those requiring a TMD. However due to the impact of texture modification on eating behaviour (section 1.6.1) it cannot be assumed that these findings can be extended to apply to those consuming a TMD, and therefore needs to be examined separately. Furthermore the impact of these strategies on appetite and overall food intakes, considering potential compensation at different eating occasions, also need to be evaluated before recommendations can be made. Therefore, understanding the mechanisms of appetite and the regulation of food intake are imperative when developing strategies to optimise food and energy intakes in those who may be at risk of poor intakes.

Even in healthy individuals, the regulation of food intake is extremely complex. It involves the interaction of homeostatic, behavioural, environmental, sensory and hedonic components regulated by both peripheral (PNS) and central pathways (CNS).

The biopsychological model (Figure 1.2) developed by Blundell and Tremblay (1995), facilitates a comprehensive overview of the interaction of these components by reducing the complexity of food intake regulation to three key levels; the psychological level, the physiological level and, the neurological level. The psychological level includes sensory appraisal of the food prior to and during consumption, as well as cognitive factors incorporating food behaviour and food choice. The physiological level involves metabolic factors occurring both pre and post ingestion, and finally the neurological level which includes the action of specific neurotransmitters triggered during food exposure. All of these factors/levels act both independently and synergistically to regulate and determine food intake. For clarity, each phase of the GI tract will be addressed individually and will include literature relevant to texture modified diets (with and without enrichment). Further the hormonal regulation of appetite will be addressed, considering how these pathways may be altered in the infirm.

Behavioural mechanisms (demonstrated in Figure 1.2) which are central to the regulation of food intake are 'satiation', and 'satiety'. Satiation is the process that leads to the termination of a meal, and satiety is the feeling of fullness which persists after eating, thus suppressing further food intake (Benelem 2009). Essentially, where satiation reduces the amount of food consumed at a meal (*i.e.* within an eating occasion), satiety determines the amount consumed at a subsequent meal and later

during the day (*i.e.* between meal occasions) (Almiron-Roig and Drewnowski 2003). The balance between satiation and satiety determines energy intake and therefore potentially affects energy balance.



NST; the nucleus of the tractus solarius, 5-HTc; serotonin, CART; cocaine- and amphetamine-regulated transcript, NPY; neuropeptide Y, AgRP; agouti related peptide
Satiation and satiety are circled in black, sensory specific satiety (SSS) boxed in red

Figure 1.2: Overview of the interaction of the mechanisms involved in the regulation of appetite and food intake reproduced (and amended) with permission from Elsevier: Bornet, R.J. Jardy Gennetier, AE. Jaquet, N and Stowell, J. 2007. Glycaemic response to foods: Impact on satiety and long term weight regulation. *Appetite*; 49, pp. 535-553 (originally produced by Blundell J.E. 1999. The control of appetite: Basic concepts and practical implications. *Schweiz Med Wochenschr*; 129: pp.182–8,)

As demonstrated in Figure 1.2, a range of factors can impact on satiation and satiety resulting in increases or decreases of food intakes. These may be initiated pre and/or post consumption and include cognitive, sensory, and environmental influences. This review focuses on the influences relating to a TMD and the potential strategy of enrichment to improve intakes, namely food texture and energy density. Considerations to all other potential confounders (*i.e.* aside from texture and energy density) which may be introduced when assessing eating behaviour are addressed during description of the development of the study design for the current study (chapter 2).

The response of the gastrointestinal tract to the entry of foods and nutrients can essentially be divided into three phases; cephalic, gastric and intestinal. For clarity, how these stages may impact on eating behaviour (the psychological level, the physiological level and, the neurological level) has been highlighted within Figure 1.2.

The cephalic phase includes the pre and peri-ingestive influences of sensory stimulation (Delzenne et al. 2010). These can be seen within the biopsychological model (Figure 1.2), highlighted in yellow. Starting with the pre-ingestive influences which can impact on eating behaviour, even the belief about a food (before it is seen or consumed) can impact on the satiety cascade. Brunstrom et al. (2011) conducted a study where they manipulated the beliefs of participants about the amount of fruit contained in a smoothie. Of the participants that believed that there was a smaller serving of fruit in one of the smoothies, post consumption ratings for hunger and fullness were higher and lower respectively despite the fact that both smoothies were

identical and baseline ratings were also not different. Interestingly, the participants who did not believe the smoothies differed in the quantity of fruit did not experience different appetite ratings after their consumption. Once exposed to a food, the initial assessments are made using visual and olfactory senses (Figure 1.2). These can aid in food choice and determine served portion sizes (Van der Laan et al. 2011), probably due to previous exposure to the food which either consciously or subconsciously link post ingestive feedback to the sensory properties of the food (Himaya and Louis Sylvester 1998).

Sensory attributes of foods play a major role in determining the type and quantity of food that is consumed. Based on the satiety cascade (Blundell et al. 1987) it can be seen that sensory cues (which may include the sight and aroma) about a food can activate the cephalic response of digestion. These autonomic and endocrine reflexes involved in the metabolism of food are triggered by sensory contact with foodstuffs rather than by post-ingestional consequences of food (Powley, 1977). Considering TMDs, altering the texture of foods will affect the sensory and cognitive experiences associated with the foods. The food will look different to what is usually expected which will impact on the cognitive aspects of the satiety cascade (Figure 1.2). Also altering the texture will affect the mouthfeel and perhaps alter the taste and flavour of the meal (Schiffman and Warwick, 1993).

Generally solid or more viscous foods are believed to evoke a greater level of expected satiety, than liquids and less viscous foods. Hogenkemp et al. (2011) carried out a study in which they investigated the effect of texture on expected satiation of chocolate milk and chocolate custard and concluded that there was an

increase in expected satiation with increased viscosity of the dairy products. Further enrichment of the meals, for example altering the energy density through the addition of energy dense ingredients may change the flavour, mouthfeel and texture of the meal, also potentially impacting on the cephalic phase of digestion. Texture modified diets can be perceived to be less palatable than standard texture diets (Table 1.9). It is important to ensure that the enrichment of these diets does not further reduce their rated palatability (chapter 2, section 2.1.2).

A phenomenon, which is important to the cephalic phase of digestion, is termed “sensory specific satiety “(SSS) (highlighted within Figure 1.2). This has been defined as a “greater reduction in the pleasantness of an eaten food than in the pleasantness of an uneaten food” (Rolls et al. 1983). SSS relates to the sensory characteristics of a food and not to the post-absorptive effects of the food. This is demonstrated by the rapid decline in pleasantness after ad libitum food intake, even before the food enters the intestinal tract and before intestinal absorption (Brondel et al. 2009). The oral exposure to food enhances the effects of gastric and intestinal exposure to food, on appetite and subsequent food intake (Smeets and Westerterp-Plantenga 2006).

Compared to low viscosity foods for example; beverages, foods of higher viscosity (for example milkshakes or soups) are said to provide longer orosensory stimulation (Mars et al. 2009) which may contribute to sensory fatigue and sensory specific satiety leading to early satiation. It has been shown that a longer duration or higher intensity of a sensory signal may promote satiation (Zijlstra et al. 2009; Blundell et al. 2010). Zijlstra et al. (2009) found that there was a reduction of 19% in ad libitum

consumption of custard to reach the same level of fullness when oral processing time was increased (from 3 sec to 9 sec). In this study, 22 healthy participants were required to consume chocolate custard ad libitum until satiation was reached in fixed bite sizes of either 5 g or 15 g (delivered via a peristaltic pump). Results indicated that intakes were greater with a greater bite size, and with shorter oral processing time (OPT) (intakes were 380 ± 198 g (3 sec OPT) versus 312 ± 170 g (9 sec OPT) with 5 g bite sizes, and 475 ± 176 g (3 sec OPT) versus 432 ± 163 g (9 sec OPT) with 15 g bite sizes).

Those with dysphagia or requiring a TMD may have impaired mastication and poor oral control causing food to remain in the oral cavity for longer than in healthy individuals (Groher and Crary 2010). It is reported that the elderly, even those without reported dysphagia, exhibit longer oral processing times than younger adults (Cook et al.1994; Shaw et al.1995) such that oral transit time and upper oesophageal sphincter relaxation are significantly longer in the elderly (Forster et al. 2011). These factors, (dysphagia and advancing age) which can increase OPT of foods may contribute to the observed reduced intakes in those requiring a TMD (Wright et al. 2005; Bannerman and McDermott 2009).

The gastric phase of the regulation of food intake involves gastric distension, gastric emptying as well as the production and secretion of important gut hormones. As a result of food present in the stomach, both mechanical and chemical receptors are stimulated to transmit signals to the brainstem via the vagal afferent nerves (Murphy and Bloom 2004). This stomach distension is related to satiety such that hunger ratings can decrease, and meal intake can be reduced, as demonstrated when a

balloon (inflated to a volume >400 mL) was inserted in the stomach (Geliebter et al. 1988). There is evidence that suggests ageing causes foods to pass from the fundus more rapidly (Clarkston et al. 1997). This potentially induces a more rapid filling of the distal gastric antrum (in older adults compared to younger adults) and prolongs gastric distension (Salles et al. 2009) which may enhance satiation and satiety and thus reduce overall food intakes.

There is also evidence to suggest that the texture of a meal can cause altered feelings of satiety, such that solids empty from the stomach more slowly than liquids (Himaya and Louis Sylvester 1998). Most foodstuffs prescribed within a TMD would be of a thicker texture than liquids and thus empty from the stomach more slowly. In the study by Himaya and Louis Sylvestre (1998) the effect of soup in different forms on satiation in lean and obese individuals was investigated. Based on the findings (Table 1.10), the authors suggested that the combination of the nutritive value of the chunky soup with the mixed form (solid and liquid) resulted in different rates of gastric emptying such that the sensed nutritive value delayed gastric emptying of the liquid component as well as the solid components which likely also remained in the stomach longer (until trituration was complete) leading to enduring gastric distension, thereby affecting subsequent food intake.

A study by Rolls et al. (1999b), investigating the effect of serving water alongside or combined within a meal on satiety, found that incorporating water into a casserole reduced energy intake at a subsequent test meal, but drinking the equivalent amount of water alongside the casserole did not. Not only does this demonstrate that water incorporated into a meal can increase satiety (arguably confirming the theory of

mixed solids and liquids on delayed gastric emptying (Himaya and Louis Sylvester 1998)) but this may have relevance to those prescribed a TMD. For some of the textural categories within a TMD, it is essential that the fluid component be fully incorporated into the meal such that separation of fluids does not occur. This prescription may however delay gastric emptying leading to reduced intakes in these individuals.

It appears that there may be an interactive effect between the texture of a meal and its energy content on the rate of gastric emptying (Marcini et al. 2001). In fact the rate of gastric emptying is influenced by the energy content of the meal consumed, such that the higher the energy contents of the meal the slower the rate of gastric emptying (Himaya and Louis Sylvester 1998; Marcini et al.2001). MRI technology allows researchers to visualise the effect properties (such as viscosity) have on gastric emptying thereby allowing more conclusive physiological evidence.

Marcini et al. (2001) used this technology to investigate the effect of viscosity on gastric emptying by providing subjects with four different meals varying in viscosity and energy content (Table 1.10) and recorded transition using echo-planar magnetic resonance imaging (EPI). Viscosity was altered through the addition of high or low viscosity locust bean gum and the nutrient content was altered through the addition of lipids (olive oil emulsified with sorbitan monostearate; 37%) and carbohydrate (type not specified; 63%). The “non-nutrient” meal had dextrose (16g) added in order to match the osmolality of the meals. Both meals had banana flavouring added to disguise the difference in composition. There was an additive effect of energy content and viscosity on delaying gastric emptying and also on subject’s feelings of

satiety. Interestingly energy content had a greater effect on the delay of gastric emptying than viscosity, but increased viscosity had a greater effect on the feelings of fullness than energy content. This may imply that enrichment of TMD may further delay gastric emptying resulting in prolonged periods of satiety contributing to reduced intakes.

The intestinal phase refers to both the pre absorption of nutrients including intestinal distension, and post absorption of nutrients where nutrients themselves are detected by specialist receptors in various sites of the body, providing information about nutrient status and satiety signals (Blundell, 1987). Hormones which regulate eating behaviour are released as a result of the presence of nutrients and stretch receptors throughout the GI tract. These hormones will be discussed in the subsequent section (section 1.5.1), including how they may be affected by factors such as disease state or advancing age. If the rates at which foods are emptied from the stomach are delayed by changing the texture and energy density of the food (as discussed above), this may delay the activation of these signals and hence prolong satiety. It is unclear if the release of these hormones can be directly related to a quantity of nutrient, or if factors such as texture would impact on these signals to a point where they could be used to make inferences about their impact on appetite.

1.5.1. An overview of GI hormones involved in the regulation of food intake

When food has been consumed signals from stretch receptors and mechanoreceptors or from chemoreceptors that respond to the products of digestion (sugars, fatty acids, amino acids and peptides) are transmitted via the vagus nerve to the hind brain for

integration (Dulloo and Schutz 2011). A number of gut hormones are secreted acting directly on areas of the brain to indicate satiety and these contribute to the maintenance of energy balance. These include episodic regulators of energy balance; and tonic regulators of energy balance. Cholecystokinin (CCK), Glucagon-like peptide-1 (GLP-1), Gastric inhibitory peptide (GIP), and peptide YY (PYY) are all short term regulators of energy balance, all of which are released after food consumption and are involved in the reduction of appetite (Suzuki et al. 2010). Another episodic regulator is ghrelin, however this hormone stimulates appetite.

In response to the presence of nutrients CCK is released, which is a hormone produced by the endocrine L cells in the duodenum and jejunum, and is involved in satiation (Suzuki et al. 2010), thereby reducing meal size. This hormone also plays a role in gastric emptying with high levels of CCK said to inhibit gastric emptying (Liddle et al. 1986). CCK also stimulates pancreatic enzyme secretion and gall bladder contraction, playing a role in digestion. Older adults seem to be more sensitive to CCK than younger adults (Wren 2008) therefore this may cause an earlier reduction in meal size compared to that experienced by younger adults. It is likely that this physiological difference observed with advancing age contributes to their reduced food intakes (section 1.1.2). This heightened sensitivity may also lead to prolonged periods of satiety as it has been shown that CCK inhibits gastric emptying (Liddle et al. 1986).

CCK plasma levels have been found to be elevated in critically ill patients, and those in chronic nutrient depletion or experiencing malnutrition (Nguyen et al. 2007). Thus those who are ill may regulate food intake differently such that the ability to meet

adequate food intake is compromised. Prolonged periods of satiety may contribute to reduced overall food and energy intakes. This may also result in strategies such as between meal snacks or ONS being unsuccessful in those with elevated CCK (*i.e.* the ill) and in those sensitive to CCK (*i.e.* older adults). As consumption will be poor for those with prolonged periods of satiety, increasing the energy density of meals served at set meals times may allow greater energy intakes. Although it is unclear if CCK is released proportionately to energy/nutrient density of the food consumed.

Due to its involvement in initiating satiation, and delaying gastric emptying, if greater energy consumption results in greater CCK release, appetite and food intakes may be further reduced. Evidence in rodents suggests that exposure to high fat diets results in the attenuation of the inhibitory effect of CCK on energy intake, and gastric emptying (Covasa and Ritter 1998; 2001). In human studies (healthy, young adults), similar, yet smaller, observations have been made, however with no resulting impact on food intake (French et al. 1995; Boyd et al. 2003). A more recent study aimed to investigate if exposure to high fat diets increases the satiating effects of CCK, specifically in older adults (Tai et al. 2010). Results demonstrated that fasting circulating CCK levels were unaffected after exposure to a high fat diet (approximately 43% of energy from fat compared to 25 % energy from fat) for two weeks.

Researchers (Tai et al. 2010) also evaluated if older adults became further desensitised to CCK, with increased fat exposure. However, they demonstrated that there was no effect on appetite, or energy intake in response to CCK-8 infusion after exposure to a high fat supplement diet for two weeks. These findings suggest, that

enriching the diet, with fat, may increase energy intakes without causing a reduction in absolute food intake (g) due to alterations in CCK sensitivity. It is unclear however, if other appetite regulation pathways would be affected by this dietary alteration, (*i.e.* enrichment through the addition of fat). After all, the regulation of food intake is controlled by multiple mechanisms, (Morley 2001) which involve hormones other than CCK in isolation.

Another hormone involved in the regulation of food intake is glucagon like peptide-1 (GLP-1). GLP-1 is an incretin hormone, produced primarily in the ileum in response to nutrients, stimulating insulin and inhibiting glucagon (Harrold 2012). Little is known however about the release of GLP-1 to specific foods (de Graaf 2004). It is thought to stimulate the 'ileal break' that allows a moderate and stable flow of nutrients from the stomach to the small intestines (de Graaf et al. 2004). Another hormone (GIP) acts alongside GLP-1 (Green et al. 2004) and is released in response to both glucose and fat ingestion (Suzuki et al. 2010).

It does not appear that GLP-1 concentrations differ depending on the age of the individual (McIntosh et al. 1999). Although this study included only men, and had a small sample size, it demonstrated that after fasting and after infusions of lipids and glucose, that plasma GLP-1 concentrations did not differ between young and older subjects. Most studies surrounding GLP-1 relate to exogenous administration of the hormone (particularly potential treatments for diabetes and obesity (through the stimulation of insulin release)) rather than assessing concentrations of circulating plasma GLP-1 as a result of various clinical conditions. It is therefore unclear what impact disease may have on GLP-1 release.

Recent research (in rats) uncovered that two cytokines, interleukin-6 (IL-6) and interleukin-1 (IL-1), which are key regulators of the inflammatory response (Tsakiri et al. 2008) mediate anti-obesity effects of GLP-1 receptor stimulation (Shirazi et al. 2013). In fact it was demonstrated that pharmacological disruption of CNS IL-1 receptor or IL-6 biological activity attenuated anorexia and body weight loss (Shirazi et al. 2013). This may allude to disruption of GLP-1 sensitivity during disease, resulting in weight loss; however more evidence is needed, including human studies relating to the concentration of plasma GLP-1 in the ill.

Another hormone involved in the regulation of eating behaviour; PYY is released (mainly from the distal gastrointestinal tract) stimulating the Y2 receptor in the hypothalamus. It should be mentioned that CCK is actually thought to be involved in the mediation of the initial post prandial release of PYY (Nguyen et al. 2007), demonstrating the complexity of hormone interactions relating to food intake regulation. The Y2 receptor inhibits the release of neuropeptide Y, the most potent CNS stimulant of appetite (de Graaf 2004) thus PYY is involved in the reduction of appetite.

Elevated levels of PYY are observed in those who are critically ill and malnourished (Nguyen et al. 2007) which puts these individuals at further risk of poor intakes due to reduced appetite. Conversely, in healthy individuals fasting has shown the potential to suppress the secretion of PYY (Adrian et al. 1985). Again this suggests that those who are ill may regulate food differently such that intakes are compromised. It does not appear that PYY concentrations differ depending on the age of the individual (Macintosh et al. 1999), and therefore is not thought to

contribute to the anorexia of aging. There is however a need for more studies, specifically evaluating circulating levels of PYY in older adults to confirm this.

Ghrelin, which is secreted by the stomach, is the only known hormone involved in meal initiation. It increases after food deprivation and decreases after food consumption (Delzenne et al. 2010). It is in fact the only known circulating factor to increase hunger (Dulloo and Schutz 2011) and when administered experimentally stimulates appetite, and increases food intake (Benelem 2009). Two studies have reported circulating ghrelin concentrations to be lower in healthy young compared to healthy old adults (Rigamonti et al. 2002; Sturm et al. 2003). This could contribute to reduced motivation to eat in older adults.

However, it was also acknowledged that increasing body fat, is associated with decreasing ghrelin concentrations, and the older subjects had higher body mass indices (BMIs) than the young subjects in both studies. It should however be considered that the interpretation of BMI indexes can change with advancing age (Cook et al. 2005) and therefore may not translate to adiposity, but rather to a decrease in height (reduced stature) associated with ageing. Therefore, the impact of age, when body fat is matched is unclear.

The aforementioned hormones are released in response to a meal or nutrient and are considered short term (episodic) signals of appetite. Hormones which serve as long term (tonic) regulators of energy balance include leptin and insulin. Leptin is the product of the *ob* gene synthesised mainly by adipose tissue acting to provide information about the availability of body fat stores to the hypothalamus (de Graaf 2004). It is released into the circulation acting on hypothalamic receptors to induce

satiety (Dulloo and Schutz 2011), reduce food intake and increases resting metabolic rate (Morley 2001). Low leptin levels can stimulate feeding arguably as it was physiologically intended to signal starvation (Otero et al. 2005) to stimulate feeding. Leptin is also considered as a pro-inflammatory cytokine therefore links to both the neuroendocrine system (as a hormone) and the immune system (as a cytokine) (Otero et al. 2005). It has been discovered that leptin synthesis increases in response to acute infection, sepsis and secretion of inflammatory mediators (Otero et al. 2005). There is however evidence of leptin resistance occurring such that high circulating leptin levels do not inhibit feeding, which may be associated with obesity (Benelem 2009).

Insulin is produced by the pancreas and mainly functions to regulate carbohydrate and fat metabolism. After a meal, insulin levels rise rapidly which reduces the concentration of glucose in response to carbohydrate ingestion. Plasma levels of insulin are directly related to level of fat such that during positive energy balance plasma insulin levels are increased whereas in negative energy balance plasma insulin levels fall (Arora 2006). It is thought that the cytokine interleukin-6 (IL-6), which is activated during the inflammatory response, may enhance insulin secretion by stimulating peripheral GLP-1 production (Ellingsgaard et al. 2011).

It is clear that there is a complex interplay of hormones involved in the regulation of appetite and food intake that appear to be disrupted during periods of inflammation for example in illness, and also with ageing. It is likely that these alterations in hormones are involved in the early satiety and reduced food intakes observed in those receiving a texture modified diet. There are no specific data on the gastro intestinal hormonal status of dysphagic individuals however it would be useful to

investigate further as healthy subjects previously demonstrated no effect on gastro intestinal hormones with altered texture (Zijlstra et al. 2009) suggesting that the reduced intakes in dysphagic individuals is not just a consequence of the prescribed texture of the foods consumed.

1.6. External factors influencing eating behaviour: Focus on food form and energy density

Eating behaviour is not only modulated by the array of individual physiological and behavioural factors (section 1.5), but it is also influenced by external factors. These include; the eating environment and also the physical properties of the foods presented and consumed. As this current study is specifically interested in the potential strategy of enriching texture modified diets for improving energy intakes, this section will appraise the literature surrounding the physical properties of food; namely food form (texture) and energy density, and discuss their impact on eating behaviour.

An overview of the evidence from the experimental literature (investigating food form and energy density on eating behaviour) and how this may relate specifically to those requiring a texture modified diet (with or without enrichment) will be discussed. Additional detail of these discussed studies, including samples, study designs, foods studied, outcomes are summarised in Tables 1.10 (texture/ food form) and 1.11 (energy density/ enrichment). Specific considerations to all additional

factors which may influence eating behaviour are addressed separately in chapter 2 within the description of the development and design of the current study.

1.6.1 The influence of food form on eating behaviour:

The impact of texture on eating behaviour has been extensively researched in experimental studies (in healthy individuals). Despite the plethora of studies in this area, it is difficult to establish a directional hypothesis as these have produced equivocal results. Evidence exists which suggests that foods consumed as solids (or foods that have higher viscosity) are more satiating and/or promote greater satiety than liquids (or foods that have lower viscosity), as demonstrated in fruit, and milkshakes (Haber et al. 1977; Bolton et al. 1981; Mattes and Campbell 2009; Flood-Obbagy and Rolls 2009).

Despite this there is evidence that suggests that foods with more fluid like properties such as soups can be satiating, even causing reductions in intakes at subsequent meals (Flood and Rolls 2007) or even that soups may impact on satiety more than solids (Rolls et al. 1990; Mattes 2005). It has also been shown that the form of a food has no effect on appetite and/or food intake (Mattes and Rothacker 2001; Mattes 2005; Flood and Rolls 2007; Zijlstra et al. 2009) as demonstrated in soups and milkshakes of varying form. It is possible that the lack of consistency in the studies conducted could be partially attributed to confounders introduced by the large variety of foods studied, and the designs of the studies used. These studies will be discussed with attention to how these may relate to texture modified diets.

First and foremost, there appears to be a lack of clarity in the literature regarding the investigation of texture and viscosity on appetite. A number of researchers consider these properties as interchangeable; however this is not the case. From a materials science perspective, foods can be divided into three main categories; solid, semi-solid or liquid. Solid foods are those that require mastication in order to reduce particle size before swallowing (Mioche et al. 2004). Semi solids require a force to initiate flow (*i.e.* transit from oral cavity to the pharynx and so on) but do not require mastication. Liquids are consumed without mastication and exhibit very short oral processing time (Foegarding et al. 2010).

Within TMDs, it should be considered that suitable foods with varying degrees of modification tend to fall within the solid and semi-solid categories. For those unable to engage the swallowing reflex, liquids will likely not be safely tolerated and hence a thickened fluid, representing a semi-solid texture is prescribed. It has already been discussed that TMD's lack quantitative definition (section 1.4) which makes it difficult to directly compare and relate most experimental studies to the subjectively described textures within a TMD. However no studies have specifically investigated meals designed to meet textural categories of a TMD on eating behaviour, as of yet. Therefore these controlled experimental studies provide useful insight into how meals of various textures and viscosities, may impact on eating behaviour.

Studies which have demonstrated that solids are more satiating (*i.e.* reduce intakes within a meal occasion) and/or result in greater impacts on satiety (*i.e.* reduce energy intakes at the next eating occasion/ or prolong the period of time until the next eating occasion) than less solid counterparts have used milkshakes (De Wijk et al. 2008; Zijlstra et al. 2008; Mattes and Rothacker 2009) and fruit (Flood-Obbagy and Rolls

2009; Mattes and Campbell 2009). These particular foodstuffs can be can be useful for assessing individual physical alterations of foods and their impact on eating behaviour, as they can be developed to control many confounders that may be introduced when assessing appetite. For example, milkshakes can be developed to be matched for energy content, energy density, macronutrient content, and palatability and volume, all of which could independently impact on eating behaviour (discussed in detail, when considering the design of experimental studies assessing appetite, in chapter 2).

Fruit can also have its form modified whilst maintaining energy density, weight, palatability and energy content (Flood-Obbagy and Rolls 2009). However when modifying the texture of fruit (and also true for vegetables), the volume may be altered (generally reduced) due to structural changes encountered during blending. Whilst the volume could be matched (*i.e.* by increasing the volume with the addition of fluids) after initial modification, this would result in an alteration in energy density, which also impacts on eating behaviour (discussed subsequently, Table 1.11).

Even the perceived volume of a product has been shown to alter expectations around satiation with larger volumes being perceived as being more satiating (Brunstrom et al. 2010). Physiologically, gastric distension promotes satiation (*i.e.* reduced within meal intakes) independently of nutrient content (Geliebter et al. 1988; Phillips and Powley 2010). Marcini et al. (2001) also reported good correlations between gastric volumes and satiety indicating delayed gastric emptying with greater gastric volumes. Interestingly, Marcini et al. (2001) also found that increased viscosity,

through the addition of either a low or high viscosity locust bean gum, of the same volume of food resulted in higher feelings of fullness.

This may have relevance when designing meals suitable for a TMD, particularly when thickeners have been added to stabilise their form, by binding water and increasing the viscosity. If increasing the viscosity of the same volume of food does increase feelings of fullness, smaller portions of TMD meals may be more easily tolerated. Increases in daily energy intakes were not observed however in a study which investigated altered meal patterns (consisting of small portions and greater meal frequency) of a TMD (Taylor and Barr 2006) (discussed in section 1.4.4).

Experimental appetite studies investigating the effects of fruit in different forms (solid, semi-solid and liquid) tend to demonstrate that fruit preloads consumed in their solid form exert a greater negative impact on subsequent energy intake (*i.e.* induce a greater satiety effect) than in their semi-solid or liquid forms (Bolton et al. 1981; Flood-Obbagy and Rolls 2009; Mattes and Campbell 2009). For example, a study by Flood-Obbagy and Rolls (2009) demonstrated that subjects consumed significantly less energy from a test meal after consuming apple segments compared to apple sauce and two juices (with or without fibre).

This suggests that consuming the fruit in a more solid form produced a hierarchy in satiety effect (as determined by energy intake at the next eating occasion); apple segments > apple puree > apple juices. Differences in volumes were observed in this fruit based study which may have played a role in the detected trend, however when the volume was matched for the solid and semi-solid there was still an effect on test meal intake and subjective feelings of satiety. The author did note that the chewing

time differed between test products, being greater for the solid compared to the semi-solid and liquid. This may have contributed to the observed increase on satiety with the solid, as it has been demonstrated that increasing the number of chews of each mouthful of food can lead to reduced energy intake (Li et al. 2011; Higgs et al. 2013).

Interestingly in the study by Flood-Obbagy and Rolls (2009), the two juices (with or without fibre) did not differ in satiety effect (*i.e.* no difference on subsequent energy intake). Within TMDs, fruits may be excluded from some of the textural categories of the diet, due to seeds, husks and fibrous material which can make them unsuitable for modification. In some cases blended fruit may be sieved to remove fibrous material, allowing the production of a homogenous texture, as described in the guidelines (BDA 2012a). Based on the findings by Flood-Obbagy and Rolls (2009) it may be possible to replace the fibre lost from sieving with fibre (albeit in a soluble form, rather than the mix of soluble and insoluble form that was removed) without impacting on satiety by delaying or reducing subsequent meal intakes.

Mattes and Campbell, (2009) investigated the effect of food form (using fruit) and timing of ingestion (*i.e.* a preload consumed alongside a meal, or two hours later as a snack) on appetite and energy intakes. Similarly to the findings of the study by Flood- Obbagy and Rolls (2009), when the preload was consumed alongside lunch, reductions in ratings for hunger were greatest for the apple (solid) followed by the apple sauce (semi-solid) and then the juice (liquid).

Mattes and Campbell, (2009), also demonstrated the effect of food form on satiety as measured by the period until the next eating occasion (which authors defined as

consumption of >100 kcal). This was shortest for the liquid, followed by the semi-solid and the longest time interval was observed for the solid, although there was no difference in subsequent energy intake between the conditions (when consumed with the meal, or two hours later as a snack). When the preload was consumed as a snack it appeared that the solid apple had a stronger suppressive appetitive effect, with the juice and semi-solid having no effect on mean hunger or fullness ratings.

This may imply that consuming nutrients in these forms (such as liquid or semi-solid based foods and/or supplements (ONS)) as a snack (*i.e.* outside usual meal times) could play a role in hospital settings to improve intakes, without negatively impacting on appetite sensations leading to reductions in intakes elsewhere. For those prescribed a TMD however, this may imply that those who cannot tolerate foods with fluid like properties may not have the same opportunity to improve their intakes without suppressing subsequent appetite.

One randomised crossover study specifically evaluated the effect of two meal replacement products, that differed in form, (*i.e.* liquid (vanilla *Ensure*) and solid (*Ensure* cinnamon and Oat N Raisin nutrition and energy bar)) that may be offered in a clinical setting (Stull et al. 2008) using a preload design. Two hours after consuming the preload subjects were served ad libitum oatmeal to consume until satiation was reached. Ratings for hunger were suppressed significantly less ($p=0.04$) after consuming the liquid compared to the solid. Also, subjects consumed on average 13.4% more oatmeal after the liquid compared to the solid.

Although the preloads contained comparable energy and macronutrient content they were quite different in terms of ingredients. The solid product contained oats and as

the test meal was oat based it is possible that this affected intakes due to the phenomenon of sensory-specific satiety (section 1.5). Although the participants were not aware that the product contained oats so this effect may not be as strong as if they had been aware, as indicated by the study by Brunstrom et al. 2011 discussed earlier.

Despite the differences in physical properties (product type and ingredients) of the products being investigated in this study which likely confounded the results (chapter 2, section 2.1.2, Table 2.1), it is interesting as the study was carried out in older adults (mean (\pm SD) 62 ± 2 years) which most studies investigating the impact of texture on appetite are not. Whilst this study, like the study by Mattes and Campbell (2009), demonstrated that liquids had less of a suppressive impact on satiety (*i.e.* subsequent meal intakes), these may not always be suitable for provision within a TMD.

The evidence that foods in more solid forms suppress satiety (*i.e.* prolong the time period until the next eating occasion, or reduce subsequent meal energy intakes) more than less solid forms (semi-solids or liquids) has not only been demonstrated in fruit based studies. This trend has also been observed using drinks and milkshakes of various viscosities. It should be pointed out that the studies discussed so far have compared solids, semi-solids and liquids which have substantial textural differences (Table 1.10). In a TMD it is likely that the foods prescribed will fall within narrower textural ranges, for example; Texture C and Texture B are both described as being “pureed” with Texture C being thicker, or more viscous than Texture B. It is therefore useful to assess the impact of different viscosities on eating behaviour within one of these categories, (*i.e.* semi-solids). Zijlstra et al. (2008) investigated the effect of food viscosity on ad libitum food intake of two milkshakes, differing in

viscosity. Although both products were equal in palatability, macronutrient composition and energy density, subjects consumed 30% more of a liquid versus a semi solid chocolate flavoured product (mean \pm SD intake 809 \pm 396 g compared to 566 \pm 311 g respectively, $p < 0.0001$) offered in a blinded box with a thick straw). This study demonstrates that foods in more viscous states are more satiating (*i.e.* reduce within meal intakes).

A follow up study compared the effect of the same products on appetite and gastrointestinal hormones. A small effect of viscosity on appetite ratings was observed, with the more viscous product (semi solid) causing higher ratings for fullness ($p = 0.03$). However there was no clear effect of viscosity on the postprandial responses of ghrelin, CCK and GLP-1 (Zijlstra et al. 2009). Subjects were then presented with a test meal (chocolate cake) after consumption of the liquid and semi-solid preloads, although no clear effect of the two products on subsequent ad libitum intake was noted. Authors suggested that viscosity may be involved in the process of satiation rather than satiety. Whilst this may appear to be the case, the method of measuring satiety in this study was by ad libitum consumption of a chocolate cake. Perhaps here, the typical high palatability of the test meal (chocolate cake) overrode feelings of fullness.

It has already been discussed that Mattes and Campbell (2009), demonstrated the effect of food form on satiety, as measured by the period of time until the next significant eating occasion. As this was defined by the consumption of a meal >100 kcal, it is likely that this more accurately reflected motivation to eat as participants were not presented with a specific meal, but rather left to decide their individual

subsequent food intake. Also, the studies cannot be directly compared as the foods studied were very different, and the differences in textures more extreme in the study by Mattes and Campbell (2009).

Mattes and Rothacker (2001) measured the impact of two milkshakes matched for volume, energy content, and macronutrient content, but varying in viscosity (600 cP vs. 16,000 cP) on satiety. Differences in viscosity were achieved through the addition of less than 0.1g of microcrystalline cellulose to the more viscous shake. Following ingestion of the more viscous shake, hunger ratings were significantly lower, and remained lower even four hours after consumption. This demonstrates that foods in more viscous forms exert a greater reduction on subsequent appetite (hunger) responses. Although energy intakes at the next eating occasion were lower after consumption of the thick shake (519 ± 60 kcal), compared to the thin shake (488 ± 53 kcal) this was not significant (31 kcal). The study did not describe how participants ingested the milkshake (e.g. spoon or straw), and perhaps this affected the study outcomes. It is interesting to note that de Wijk et al. (2008) demonstrated that after the confounder of 'bite effort' is eliminated, semi-solids and liquids are found to be equally satiating.

In this study (de Wijk et al. 2008) participants were presented with two milk based chocolate flavoured drinks matched for macronutrient composition, energy content and energy density in both a liquid and semi-solid form to consume within 15 minutes at alerted times through a thick straw. On average participants consumed 47% more of the liquid product compared to the semi-solid (413 ± 73 g versus 222 ± 9 g), however there was no difference in rated satiety parameters (hunger, fullness,

desire to eat, prospective consumption). Bite sizes were significantly smaller for the semi-solid than for the liquid (4.6 ± 1 g versus 9.5 ± 1.7 g) and when researchers controlled for this by delivering both products via a pump, the previous difference in intake (g) disappeared (522 ± 55 g versus 545 ± 70 g of the liquid versus the semi-solid respectively). This finding may be important when considering individuals who may need to exert greater effort to consume thickened liquids due to weakened facial muscles, for example those with dysphagia. This increased bite effort may lead to fatigue and thus reduce the quantity of food and resulting energy intakes consumed.

The study discussed above (de Wijk et al. 2008) highlights the importance of the oral phase in the contribution to eating behaviour, particularly with bite effort (de Wijk et al. 2008), and oral exposure time (Flood-Obbagy and Rolls 2009)). It is therefore important to consider how foods and beverages behave in the oral cavity, and how this may impact on appetite and food intakes.

This may be particularly relevant for those prescribed a TMD who cannot safely alter the texture of the meals they can consume (from their dietary prescription) without increasing risk of aspiration. It may be that these individuals are consuming food textures that result in greater oral exposure time and consequently early satiation and/or prolonged satiety. Oral exposure time may be further increased in these individuals as those with dysphagia can have limited control over food in the oral cavity which may lead to longer exposure times (Groher and Crary 2010). Perhaps this adds to the observed reduced intakes of TMD in the clinical setting, in patients with dysphagia (Wright et al. 2005). In fact it appears that intakes decrease with the greater degree of modification the meal undergoes, which is essentially the opposite

trend to what has been described in experimental studies. This suggests that it is not just the texture of the food that is negatively impacting on food intakes. Although it is also not known what effect altering the energy density of these altered texture meals have on appetite and food intakes and thus needs to be evaluated further.

From the studies investigating the impact of food form on eating behaviour that have been reviewed so far, key trends can be identified. It appears that; solids cause greater satiety (*i.e.* reduced subsequent meal energy intake) compared to semi-solids and liquids (Stull et al. 2008; Flood-Obbagy and Rolls 2009). It also seems that solids cause greater satiety (*i.e.* prolonged delay until the next eating occasion) compared to semi-solids and liquids (Mattes and Campbell 2009). Further, solids result in lower ratings of subjective hunger, and higher ratings of subjective fullness compared to semi-solids and liquids (Mattes and Campbell 2009). It has also been demonstrated that viscous milk based beverages are more satiating (*i.e.* result in reduced within meal intakes) than their less viscous counterparts (Zijlstra et al. 2008) although this effect disappears when bite effort is controlled (de Wijk et al. 2008). Increasing the viscosity of milk based beverages affects appetite responses in healthy adults, resulting in higher ratings for fullness and lower ratings for hunger (Mattes and Rothacker 2001; Zijlstra et al. 2008). Despite the differences in subjective appetite responses, no clear effect on subsequent energy intake or on gastro-intestinal hormones related to appetite have been found (Zijlstra et al. 2009).

Thus it has been demonstrated that in the experimental setting, liquids and less viscous materials result in greater within meal intakes (alluding to poor impact on satiation), reduced feeling of hunger (alluding to reduced impact on negative appetite

feedback response) and shorter periods until the next meal occasion (alluding to reduced satiety). In fact, it is thought that liquids actually fail to initiate satiation and satiety feedback and it is this fact which may be contributing to the obesity epidemic as these calories are consumed without the body registering them or compensating for them by reducing intakes elsewhere (Almiron-Roig and Drewnowski 2003). However, studies have shown that foods representing more liquid forms, such as soups can be satiating, even more so than solids in some cases (Rolls et al. 1990; Mattes 2005).

Two other studies (discussed within section 1.5) confirm the ability of soups to induce satiety, despite their liquid nature or components (Himaya and Louis Sylvestre, 1998; Rolls et al. 1999b). In fact in the study by Rolls et al. (1999b) it was demonstrated that subjects consumed 16% less energy at lunch after consuming a chicken soup compared to a chicken casserole and a chicken casserole with water, demonstrating again the satiating capacity of soups compared to non-soup foods equal in composition and/or volume.

Rolls et al. (1995b) found no difference in satiety effect of three equicaloric (50 kcal) preloads of tomato soup, melon, cheese and crackers. A difference was found however when the energy content was increased to 200 kcal (by increasing the portions) which showed that when soup was consumed as a first course, subsequent intake was reduced compared to the other two preloads, suggesting a synergistic effect of texture and energy. Although the portion was increased resulting in differences in volume of preload consumed, the difference in volume between the soup and melon was small and dishes were matched for energy density, yet energy

intake consumed after the soup was significantly less than after the melon ($F_{(1,11)} = 5.04$, $p < 0.05$).

It is important to note that the preloads did vary in other properties namely macronutrient content, energy density, volume (particularly the cheese on crackers compared to the other two preloads), taste (sweet melon versus savoury cheese and crackers and soup) and weight which are likely to have added to the effect. The study does however show the potential of soups, or liquids, being more satiating than solid foods when matched for energy content. It may also indicate the possibility of a maximum enrichment level.

It is accepted that there is bound to be a maximum enrichment level that will be aesthetically acceptable. It was demonstrated in a small study ($n=11$ females), in our laboratory that higher levels of enrichment were found to have a detrimental effect on the aesthetic ratings of soup (texture $F = 4.01$, $p = 0.038$) and milk-pudding (taste $F = 3.71$, $p = 0.034$; texture $F = 7.55$, $p = 0.006$; pleasantness $F = 4.56$, $p = 0.021$; aftertaste $F = 4.47$, $p = 0.015$) (Memmott et al. 2010). Findings from the study by Rolls et al. (1990) suggests that there may also be a maximum threshold for which a TMD can be enriched without impacting on satiation. This theory needs to be investigated further however, as there are many other factors, such as volume (*i.e.* as energy content was increased by increasing the portion) which may be confounding the results.

Another study investigated how the form of soup affects intake for both subsequent meal (lunch) and total meal intake (soup and lunch) (Flood and Rolls 2007). Subjects consumed significantly less energy (20%) from a test meal when a preload of soup

was consumed compared to no preload ($p < 0.0001$), however there was no difference between the forms of soups on energy intake at lunch. A similar trend was seen for total energy (preload plus lunch). Hunger decreased with soup compared to no soup, fullness increased with consumption of soup versus no soup however there was no difference between soups of different forms on appetite responses. Although all soups were rated to be acceptable, they did differ in pleasantness (taste and appearance) (chunky soup and chunky pureed soup were rated significantly higher than the other two soup forms for taste and appearance) which can be a determinant of food intake (Blundell and Stubbs 1999; Stubbs and Whybrow 2004). Expected satiety as rated by VAS differed across conditions with the chunky pureed and pureed soups expected to be more filling compared to the chunky soups and broth and vegetable. Participants also expected the thicker soup (chunky puree soup) to be higher in calories compared to the puree soups and chunky soup and broth and vegetables.

Since several studies have observed that eating soup can reduce hunger, increase fullness, and reduce subsequent test meal intake, it appears these can induce satiety despite their liquid properties. Authors conducting these studies have provided theories for the mechanisms involved in the satiating capacity of soups. Characteristics of the soups such as the amount consumed, temperature, fat content, energy content, viscosity, as well as the form of soup (chunky, smooth, mixed) have all been proposed (Flood and Rolls 2007). Another explanation is the apparent expected satiety of viscous foods, of which soups could be perceived. As discussed earlier (within this section) expected satiety can have an impact on appetite and satiety (Hogenkemp et al. 2011).

It was previously discussed that solids have been found to be more satiating than liquids, and this is perhaps due to the longer oral processing time, which liquid products do not tend to exhibit. Soup however is typically served hot and therefore may actually spend longer in the oral cavity compared to cooler liquids or pureed fruits in order for the temperature to match the oral temperature (de Wijk et al. 2011). Interestingly in a study by Flood and Rolls (2007), there was no difference in appetite between the forms of soup; however there was also no difference in the temperature the soups were served (65 °C) nor in the time taken to consume the soup suggesting similar times of oral exposure.

When considering application to a TMD, the textures and viscosities of the foods used in the experimental studies discussed so far may not be suitable for provision within a TMD. Some of the foods discussed, for example juices and soups may be too thin leading to aspiration and may in fact need to be thickened in practice resulting in the production of foods with a more semi-solid form, thus potentially altering their impact on eating behaviour.

Similarly, solid foods such as raw apples may be too hard to include in a TMD and may need to be modified to represent a less solid form. Also neither of these individual foodstuffs (fruit or milkshakes) would constitute a full meal in a clinical setting. These findings should therefore be applied cautiously to a population who may require a TMD. There are no known studies thus far in healthy subjects investigating the impact of foods of different forms, designed specifically to match the requirements of a TMD. Therefore studies investigating texture modified meals that are specifically developed in line with the descriptors are justified.

Table 1.10: Summary of studies investigating food form on eating behaviour

Author (s)	Foods/ textures	Study Design	Satiation	Satiety	Appetite
Bolton et al. 1981 n = 9 Healthy subjects	Grape juice (323 ml) and grapes (339 g) Orange juice (610 ml) and oranges (626 g)	Repeated measures crossover design	Not measured	Not measured	Oranges and grapes evoked more satiety (as shown by appetite scales) than the corresponding amount of juice. Return of hunger occurred earlier after juice (at 60 mins) compared to solid fruit.
Himaya Louis Sylvestre 1998 n=12 lean, and n= 10 overweight Healthy subjects	Vegetable puree and vegetable soup and solid vegetable and water	Preload followed by second course of tabouleh and third course of vanilla custard (both ad libitum) and then dinner later (canned ravioli, apple sauce and butter cookies)	Preload (300 g) consumed in entirety	Energy intake reduced after chunky soup (lean and obese) and also reduced at dinner after chunky soup (obese group only)	Significantly greater suppression in hunger after chunky soup vs. vegetable and water. Difference between chunky soup and strained veg soup failed to reach significance (p=0.08)
Mattes and Rothacker 2001 n = 84 adults (48 +/- 13 years) Healthy subjects	Low viscosity vanilla milkshake (600 cP) and high viscosity vanilla milkshake (16,000 cP)	Double blind, crossover, preload design followed by period of time where food was proscribed (4 hours) and then a diet record of all food and drink consumed	325 ml of each shake consumed in entirety in 10 mins	No difference in inter-meal interval. Energy intake at first meal not different (higher after thin shake) Daily energy intake not different (higher on days thin shake consumed)	Hunger: Ratings reduced for both shakes but remained lower for longer after thick shake. Hunger ratings sig lower after thick shake at time points (1h, 2h, and 4 h)
Flood and Rolls, 2007 n= 60 adults Healthy subjects	Broth and vegetables (served separately), chunky vegetable soup, chunky-puree vegetable soup, pureed vegetable soup or no preload	Preload followed by test meal (cheese tortellini and tomato sauce)	Preload consumed in entirety within 12 mins. Test meal served after 15 mins	Less energy consumed from test meal on days soup vs. no soup (p< 0.0001) however no difference between forms of soup. Daily energy intake not measured.	No significant differences in ratings of hunger, fullness, thirst and prospective consumption across types of soups at any time points. After lunch no difference in appetite ratings (although subjects consumed less energy and a greater weight of food when a preload of soup vs. no soup)
Notes:	The chunky (53.2 ± 3.0 mm) and chunky-pureed soup (53.6 ± 3.0 mm) were rated to be more pleasant in appearance compared to the pureed soup (34.8 ± 2.8 mm) and broth a vegetables (23.5 ± 2.5 mm) (p<0.05). In terms of taste, the chunky (61.2 ± 2.8 mm) and chunky-pureed soup (61.2 ± 2.7 mm) were more palatable than the broth and vegetables (52.7 ± 3.1 mm) and the pureed soup (52.0 ± 3.0 mm (p<0.005)).				

Author (s) and subjects	Foods/ textures	Study Design	Satiation	Satiety (next eating occasion)	Appetite
Stull et al. 2008 n=24 healthy older adults (>50 years)	Liquid (Vanilla ensure) meal replacement and solid (Ensure cinnamon and Oat N Raisin nutrition and energy bar) meal replacement product	Randomised repeated measure crossover design. Preload design followed by test meal (oat based porridge) two hours later	572 g liquid and 146 g solid both 559 kcal consumed in entirety as preload	On average, subjects consumed 13.4% higher food intake (+ 40 g of oatmeal, p= 0.006) after consumption of liquid vs. solid meal replacement	Hunger: AUC for hunger was higher after consumption of liquid vs. solid. No difference in AUC for fullness, desire to eat, or preoccupation with thoughts of food between products
Zijlstra et al. 2009 n= 32 Healthy subjects	Liquid chocolate milk based drink (0.85 Pa. s) and semi sold chocolate milk based drink (7.88 Pa. s)	Randomised crossover. Preloads followed by ad lib test meal of chocolate cake	Fixed amount served (500g men, and 400g for women to consume in 15 mins). Both men and women consumed more (+ 20 g (men) and + 22 g (women)) of the liquid compared to the semi-solid	Intake (g) of chocolate cake was not different regardless of form of shake although was higher after liquid compared to semi solid (102 +/- 55 g and 96 +/- 46 g).	AUC for Desire to eat, appetite for something sweet and prospective consumption lower after semi solid vs. liquid (not significant) Fullness (AUC) higher after semi solid vs. liquid (not significant)
Flood Obbagy and Rolls, 2009 n=58 adults Healthy subjects	Apples, apple sauce, apple juice with fibre, apple juice without fibre, no preload	Repeated measures crossover design. Preload (266g, ~125 kcal) to consume in 10 mins. followed by test meal of cheese tortellini in tomato sauce 15 mins later)	Preloads consumed in entirety within 10 mins.	Subjects consumed less energy (p<0.05) from the test meal after consumption of apple segments compared to applesauce and both juices. Consumed less energy after apple sauce vs. both juices	After consumption of preload: Hunger ratings lower after apple compared to apple sauce and both juices (p=0.001). Hunger lower after apple sauce vs. juice without fibre (p=0.001) Fullness ratings greater after apple compared to apple sauce and both juices (p=0.001). Fullness greater after apple sauce compared to both juices (P=0.001) Thirst: Lower after both juices compared to apple sauce and apple (p< 0.001)
Notes	Chewing time differed for the preloads which may have had an effect on satiety, perhaps due to increased oral exposure time. Expected satiety and expected energy content was rated differently for products which may have influenced results perhaps causing a reduction in food intake if subjects believed the foods to be satiating or high in energy, as it has been shown that these cognitive beliefs about a food can play a role in food intake (Brunstrom et al. 2011)				

Author (s) and subjects	Foods/ textures	Study Design	Satiation	Satiety (next eating occasion)	Appetite
Mattes and Campbell 2009 n= 40 (20 lean and 20 obese) Healthy subjects	Apple juice, apple sauce and whole apples (with meal or 2 hours later as a snack)	Repeated measures crossover design Preload (supplement of apple juice, apple sauce or whole apples) with a meal (peanut butter and jelly sandwiches, baby carrots, and whole milk) or two hours later as a snack. Diet recall the next day for all meals consumed after session	Preload consumed in entirety	Inter-meal interval (until consumed >100 kcal): when consumed with meal: shorter when a liquid was consumed as a beverage (275 +/- 20 mins) vs. applesauce (319 +/- 18 mins) vs. whole apples (312 +/- 19 mins) Juice vs. sauce (p=0.011) juice vs. whole fruit (p= 0.085)	Hunger: Ratings lower after solid apple vs. purée and juice (at 30 mins after consumption) and sig lower after solid vs. juice at 60 mins-180 mins
Notes	Satiety: When consumed as a snack: Shorter after juice compared to sauce or solid (209 +/- 18 juice, 325 +/- 19 sauce, and 337 +/- 18 solid) Juice vs. solid (p=0.018) Juice vs. sauce (p=0.093). No effect on next meal energy intake or daily energy intake (in both conditions , i.e. with meal or alone as snack)				
Zijlstra et al. 2010 n=116 adults Healthy subjects	Luncheon meat (hard and soft) Meat replacer (hard and soft) Candy (hard and soft)	To consume ad libitum on randomised crossover test days	Ad lib intake of hard vs. soft not different however tended to be lower for hard versions	Not measured	After ad libitum intake, no difference in satiety ratings (hunger, fullness, desire to eat, appetite sweet/savoury, prospective consumption, and thirst) between soft solid and hard solid
Wright et al. (2005) n= 55 (n=25 medically stable elderly, control group and n=35 receiving a TMD)	n= 10 (category B) n= 9 (category D) n=11 (category E) n= 25 (normal diet)	Comparison of 1 day weighed food intake between two groups (unpaired)	Not measured Note: there is a lack of studies reporting absolute intakes of TMD meals on a within meal basis	Not specifically measured however , those receiving TMD consumed significantly less daily energy (535 kcal) than the control group	Not measured
Bannerman and McDermott (2011) n=30 (NHR)	n=15 standard texture diet n=15 TMD	Comparison of 3-day weighed dietary intakes (plate wastage)	Not measured	Daily energy intakes significantly reduced with TMD (257 kcal) (p= 0.024)	Not measured

Despite the conflicting results observed with food form on appetite and food intakes, one feature that does stand out is that consuming foods with low energy density prior to a meal (soup, and fruit) in a range of forms can reduce subsequent energy intake. This leads then to the question of the effect of energy density on appetite and food intake. This has particular relevance when considering the strategy of enriching texture modified diets. Studies which have demonstrated that altering the energy density of meals has the potential to improve energy intakes in standard texture diets (Gall et al. 1998; Odlund Olin et al. 1996; 2003; Silver et al. 2008)) have already been discussed (section 1.2.1).

It is however not known what effect enriching meals of various forms, such as the various textures prescribed within a TMD may have on appetite and energy intakes. For example, it is unclear if manipulating the energy density of these foods would further reduce intakes (within a meal and/or cause post-meal compensation). Furthermore the studies which have already been discussed surrounding energy density and eating behaviour were largely poorly controlled, cohort studies using infirm samples. Therefore the exact influence of energy density on intakes is not clear.

It is necessary to evaluate the literature surrounding energy density in controlled studies using specific inclusion and exclusion criteria, and standard appetite assessment methodology. These are discussed below in relation to their potential implications when applying to a clinical setting, or to those requiring an enriched meal to improve energy intakes. Further detail of the studies discussed has been collated and can be seen in Table 1.11.

1.6.2 The influence of energy density on eating behaviour

The energy density of a food refers to the amount of energy in a given weight of food or drink (kcal/g, kJ/g) and ranges from; 0 kcal/g (0 kJ/g) to 9 kcal/g (37 kJ/g) (Atwater constants (Merrill and Watt 1973)). The primary determinants of energy density are water and fat. Water contributes weight without energy therefore reduces the energy density of a food or drink. This is why texture modified diets may have reduced nutrient densities, as low or non-caloric liquids may be added during their preparation to achieve homogenous textures.

Generally water rich products such as fruit, vegetables and beverages have low energy density. Of the macronutrients, fat is the most energy dense providing 9 kcal/g (37 kJ/g) compared to carbohydrate and protein which contribute on average; 4 kcal/g (17 kJ/g). High fat foods therefore tend to be high energy dense foods. Energy density refers to the amount of metabolisable energy therefore fibre and certain fat replacement products can also reduce the energy density of food (Stubbs et al. 2000b).

Studies have shown that as the proportion of fat in a food increases, so does the energy intake. It is argued that this is because fat is extremely palatable, (Blundell and MacDiarmid 1997; French and Cecil 2001). Fat can improve the texture and flavour of foods and therefore can promote greater intakes, whilst some researchers suggest that fat is overeaten because it is not as satiating as the other macronutrients. Perhaps, enrichment of a TMD with fat based ingredients may result in greater intakes due to its high palatability and high energy density. It can be difficult to separate the effects of fat, from those of energy density on eating behaviour.

Therefore it is unclear if intakes are influenced by the fat or the energy density of the food.

Bell et al. (1998) investigated the effect of energy density independently of fat content and palatability, on food (g) and energy (kcal) intakes. Participants were provided with meals for two days in three testing sessions where meals had the energy density adjusted. This was achieved by manipulating the amount of low fibre vegetables and pasta thereby altering the energy density of the meal without largely affecting percentage contributions from macronutrients. Participants were required to consume energy adjusted entrees and compulsory low energy side dishes. Energy density did not affect the quantity of food (g) consumed therefore significantly more energy (kcal) was consumed on days when the energy dense meals were served. The difference in total energy intake was due to the difference in energy consumed from the main entrees which demonstrates that the energy density of the meal was the main determinant in energy intake. Therefore energy density had an effect on energy intake independent of macronutrient content or palatability. This suggests that, meals may have their energy density adjusted via the manipulation of any of the macronutrients; not just fat which is often used for providing energy dense meals in the clinical setting.

Another study successfully separated the effects of fat and energy density on intakes. Rolls et al. (1999c) investigated whether energy intake was affected when the energy density or the fat content of a portion of the diet (50% of each individual's habitual energy intake) was manipulated without significantly affecting rated palatability. They manipulated the diet with the addition of water and fibre (through the addition of fruit and vegetables), and by using low fat version products to create three

versions of the meals (1) low-fat, low energy density, 2) low fat, high energy density, 3) high fat, high energy density), thereby separating the effects of fat and energy density.

Results showed that when 50% of an individual's energy intake varies, the effect of energy density affects energy intake such that the weight of food consumed is constant thereby energy intake is directly related to energy density for both lean and obese women. The fat content had no effect on intakes. The low energy dense meals contained twice the amount of fibre compared to the high energy dense. This study demonstrates that it may be possible to enrich a portion of the diet, rather than the total diet to improve intakes in the hospital setting. This may lead to greater intakes over time, with greater compliance due to greater variation in meals (*i.e.* not all meals high in energy density).

It is repeatedly demonstrated that consuming a low-energy dense preload (*i.e.* fruit, salad, and soup) prior to a test meal results in reduced energy intake at the subsequent meal. Studies demonstrating this using fruit and soups have been discussed already (Flood and Rolls 2007; Obbagy Flood and Rolls 2009). Similarly, Rolls et al. (2004) investigated the effect of serving salad preloads varying in energy density and portion size on energy intake at a subsequent lunch meal (pasta). The energy density was adjusted by varying the amount and type of dressing and cheese added, resulting in energy densities of 0.33, 0.67, 1.33 kcal/g (largely due to difference in fat content). Portion sizes were either 150 g or 300 g and were to be completely consumed prior to the ad libitum test meal. Test meal energy intake was significantly reduced (98 ± 30 kcal) after consumption of the larger (300g) compulsory first course compared to the smaller compulsory (150g) first course.

The effect of energy density on subsequent test meal energy intake did not reach statistical significance ($p= 0.06$), although a slight trend reflecting lower test meal energy intakes following consumption of the salads with higher energy density (300 g portions) appeared. It was however found that compared to consuming no salad, total meal energy intake (salad and pasta) was reduced by 7% and 12% after consumption of the small and large portion of the low energy dense salad respectively. Also, when the high-energy dense salad was consumed, total meal energy intake (salad and pasta) increased by 8% and 17% for the small and large portions respectively. Ratings of hunger were affected by portion size rather than energy density with an immediate increase in fullness and prospective consumption ratings, and a decrease in ratings of hunger after consumption of the larger portion of salad compared to the smaller salad. This study suggests that energy density and portion size act synergistically to affect energy intake.

It does seem that portion size is particularly important in determining the amount of food consumed as demonstrated by the significant reduction in subsequent energy intakes after the larger salad. Perhaps this was due to an increased level of gastric distension as a result of consumption of the larger portion size. Similarly, as the larger salads were visually larger this may have impacted on appetite ratings as with the study by Hogenkemp et al. (2011), who demonstrated the effect of volume and expected satiety. This again, demonstrates the potential success of energy enriching meals to improve energy intakes, as smaller portions can be consumed whilst still allowing greater energy intakes. It does seem however that, there may be a threshold, of which a set portion of a food can be enriched to, until additional intakes are compromised.

A study by Roe et al. (2012) investigated the effect of timing of salad consumption on meal energy intakes. Interestingly a secondary variable assessing if a difference in intakes was apparent if the salad was served in both ad libitum and fixed portions. This design allowed authors to distinguish between what may happen in the laboratory (fixed) compared to more real life behaviour (ad libitum), and provides insight into the design of future studies. In the ad libitum conditions, salad energy intake was 23% greater when it was served before rather than with the main course (71 ± 3 kcal versus 58 ± 4 kcal.)

Whilst this difference represents just 13 kcal and therefore is unlikely to be clinically significant, it is interesting to observe that eating behaviour appears to be altered just by serving the meal in separate courses (as a preload compared to alongside main meal). Although it is possible that this difference was due to people's aversion to salad when they saw more food of greater choice (cheese tortellini with tomato sauce) was available. More studies should be conducted to evaluate the impact of serving meals in different courses as they may be used to inform meal delivery in an institutional setting. For example, if meals were served in separate components rather than all together on a tray, more would be consumed. It is unknown if patients may consume less at subsequent courses throughout the meal to compensate for any additional food/energy consumed at previous courses. Also it is unclear if this would be a feasible method to serve meals on the ward due to possible shortage of resources to aid with serving of meals (section 1.3.3).

There was no effect of timing of consumption on energy consumed at lunch however participants consumed less pasta after consuming the salad ad libitum compared to the fixed amount, despite the fact that less salad was consumed in the ad libitum

conditions. Similar to previous studies, consuming the low energy dense salad preload resulted in an 11% ($57 \text{ kcal} \pm 19 \text{ kcal} / 238 \pm 79 \text{ kJ}$) reduction in total energy intake compared to when no salad was consumed. Hunger ratings were significantly lower and fullness ratings were higher following the fixed quantity of salad versus the ad libitum serving which reflected self-determined intakes.

From a study design perspective it was interesting to see that ad libitum intakes were less than the compulsory serving in both conditions (when served prior to or alongside main meal). This suggests that the fixed portions served were too large to accurately reflect real life eating behaviour in these individuals, and therefore the findings may not be directly related to the energy density of the preload. These studies (Rolls et al. 2004; Roe et al. 2012) confirm that portion size plays a role in determining appetite and food intakes, such that as described earlier the larger the portion or volume of food consumed, the greater the feeling of fullness. Further, these studies demonstrate the potential of enrichment as a strategy to improve energy intakes, once the portion size is not too large.

Still, it is unclear what impact, if any, enrichment may have on subsequent energy intakes. Some evidence of energy compensation with enrichment has been observed in the clinical setting (Odlund-Olin et al. 1996), however this study included individuals who may have had altered appetite responses. Mazlan et al. (2006) investigated the effect of energy density and food weight (volume) on subsequent intake in men. They demonstrated that only partial compensation (40%) of energy intake occurred at the next meal. It may be possible that the time delay between the breakfast snack and lunch was too short (2 hours) in this design to notice differences in intakes caused by adjustment on energy density.

Interestingly, from the study by Mazlan et al. (2006) it seems that doubling the weight and doubling the energy density had similar effects in suppressing short term intake relative to a low energy dense (LED) meal. In this design on four different occasions, subjects received porridge (8.30 am) and a milkshake (10.30 am) that were altered to be LED, high-energy dense (HED) or zero intake (Table 1.11). Subjects then (from lunch time (12.30pm) until bedtime) had continuous ad libitum access to a selection of high fat, high carbohydrate or high protein foods. There were no differences in hunger ratings post lunch despite the fact that, prior to lunch, subjects were hungrier on the zero intakes and LED intake days relative to HED or 2 x LED days. Overall 24 hour hunger ratings were highest on days where no breakfast was consumed. Fullness ratings were significantly higher on the 2 x LED day compared to the other three treatment days, again demonstrating the importance of portion size in activation negative appetite feedback. Arguably this further suggests that foods can be substantially enriched (*i.e.* 50%) without suppressing future intakes, once volume is controlled.

Devitt and Mattes (2004) investigated the effect of food unit size and energy density of food intake in humans where subjects attended a laboratory on four non-consecutive days to be fed breakfast (omelette), lunch (wrap sandwiches) and dinner (pizza) with varying energy density, and /or food unit size (Table 1.11). Manipulating energy density and unit size had no effect on feelings of hunger and fullness. The manipulations also showed no effect on food intakes (g) at breakfast, lunch, and dinner, and therefore no significant difference in daily intake (g). Total daily energy intakes were significantly lower with both the LED treatments compared to HED (859 kcal and 653 kcal lower for the SFU and CFU LED meals

respectively, $p=0.05$) which reflects the difference in energy density of the manipulated food as a constant weight of food was consumed. At breakfast and lunch, energy intakes were significantly higher in the HED versions regardless of unit size. Results from this study therefore suggest that as people consume a constant weight of food the energy density of food determined increased energy intake.

The energy density of a food clearly has an effect on energy intakes (Table 1.11), as is observed in experimental studies investigating healthy individuals and also in the clinical setting studying individuals with added health complications (discussed in section 1.2.1.). Generally individuals consume a similar quantity of food regardless of energy density which therefore has a profound effect on energy intake. Appetite responses seem to be largely unaffected by alterations in energy density which shows the potential of altering energy density of meals for purposes such as weight management.

Mazlan et al. (2006) demonstrated this potential when they found that doubling the weight and doubling the energy density had similar effects in suppressing short term intake relative to the LED treatment. It certainly seems that the body's energy regulation systems monitor portions of food to a greater degree than it does the foods energy density. This could in theory result in individuals consuming too much energy if consistently consuming high energy dense meals or alternatively not consuming enough energy if constantly consuming low energy dense meals.

Whilst these experimental studies investigated altering the energy density of meals for the purpose of reducing overall energy intakes for application for obesity management, the theories may be reversed to apply to a vulnerable, undernourished

population to potentially improve energy intakes by increasing the energy density of meals to improve intakes. More work is needed however to establish suitable levels of enrichment to facilitate improved intakes long term without causing compensatory behaviour elsewhere which could negate any nutritional benefit previously achieved by enriching meals.

Table 1.11: Summary of studies investigating energy density on eating behaviour

Author and subjects	Foods and energy densities	Design	Satiation	Satiety	Appetite	Notes
Bell et al. 1998 n=18 Healthy subjects	Main entrées varying in ED (low (mean 1.02 kcal/g), medium (mean 1.17 kcal/g), high (mean 2.34 kcal/g)) Served alongside fixed portions of low ED side dishes. ED adjusted through addition of low fibre vegetables and pasta.	Within subjects, randomised, repeated measures design (Three, 3 day test sessions)	No effect of ED on weight of food consumed- therefore daily energy intakes significantly higher on the days on high ED meals (high: 1800 \pm 86.8 kcal, medium: 1519 \pm 67.1 kcal, low: 1376 \pm 42.6 kcal).	Subjects consumed significantly more energy on high ED days vs. medium ED and low ED days	No significant differences in hunger, fullness, thirst, prospective consumption, nausea before or after breakfast, lunch and dinner in any conditions of energy density.	Period of satiety not measured
Rolls et al.. 1999) n= 17 lean and 17 obese Healthy subjects	50% of each subject's usual intake of compulsory entrees had their fat and/or energy density altered ED: 4.4 or 6.7 kJ/g and Fat content: 16% or 36 % of energy from fat Served alongside ad libitum portions of side dishes.	Within subjects, repeated measures design Breakfast, lunch and dinner consumed in laboratory. All other food and drink consumed was weighed and recorded in a diary	Lean: absolute intake (g) from ad lib side dishes sig. higher in HED vs. LED conditions (LF LED 1410 \pm 104 g, LF HED 1593 \pm 111 g). Obese: absolute intake (g) from ad lib side dishes sig. higher in HED vs. LED conditions (LF LED 1689 \pm 110 g, LF HED 1860 \pm 125 g).	Total daily energy intake not different between LF LED and LF HED conditions for both lean and obese	No significant differences between conditions for hunger, and fullness. In obese group: larger increases in ratings of nausea were observed in LF LED condition vs. LF HED condition (p= 0.013).	Energy density and/or fat content altered Palatability between compulsory foods differed significantly (although small, and overall foods were well liked) This study allowed free choice of foods for the participants thereby reflecting a more real life setting. The quantity of fibre differed and it was not possible to discriminate between the types of fibre in the meal.

ED; energy dense, LED; low energy dense, HED; high energy dense, LF; low fat

Author and subjects	Foods and energy densities	Design	Satiation	Satiety	Appetite	Notes
Roe et al. 2012, n=46 women Healthy subjects	Low energy dense salad (0.33 kcal/g) served as a preload or alongside a test meal in ad libitum and compulsory portions	Repeated measures crossover designs	Ad lib salad intake was 23% greater (13 kcal) served as a preload vs. alongside a main course Note: ad lib intake of salad was less than fixed portion (300 g) when served as preload and with meal	Fixed preload: No difference in intake (kcal) at pasta meal when served prior to or alongside meal Ad lib preload: No difference in intake (kcal) at pasta meal when served prior to or alongside meal	After main meal consumed no significant effect on timing of serving salad. In fixed conditions, hunger lower and fullness higher compared to when consumed ad lib	Other variables include timing of consumption and portion size
Mazlan et al. 2006 n= 16 lean men Healthy subjects	Fixed breakfast (08.30 am) plus a snack (10.30 am) in one of four treatments (i) zero intake, 0 kJ/g (ii) low energy density (LED) 400 kJ/g (iii) high energy density (HED) 800 kJ/g (iv) 2 × LED, 400 kJ/g. Followed by ad libitum access to 15 high-protein, 15 high-fat and 15 high-carbohydrate foods.	Randomised, repeated measures crossover design	Fixed portion of breakfast (porridge) and snack (milkshake) consumed Milkshake varied in volume and/or energy density)	At lunch: absolute intakes significantly higher after LED milkshake (650 g) vs. HED milkshake (480 g) Energy intake at lunch sig higher after LED milkshake (4.2 MJ) vs. HED milkshake (3.1 MJ) Post lunch: no significant differences in energy of absolute food intake regardless of ED of milkshake consumed at breakfast Daily energy intake was significantly higher on HED and 2 x LED days compared to zero intakes and LED intake at breakfast days.	Pre-lunch period: subjects were hungrier on the zero and LED treatment relative to either the HED or 2 × LED treatments. In the period after lunch there were no significant differences in subjective hunger between conditions. Fullness sig. lower before lunch on the zero-breakfast diet and more full on the 2 × LED diet than the other 3 days	No difference in pleasantness of foods

Author and subjects	Foods and energy densities	Design	Satiation	Satiety	Appetite	Notes
Devitt and Mattes 2004 n=20 Healthy subjects	Breakfast: omelette (1.09 kcal/g or 2.19 kcal/g) Lunch: wraps (1.43 kcal/g or 3.04 kcal/g) Dinner: pizza (1.95 kcal/g or 2.57 kcal/g)	Randomised, repeated measures crossover design	No difference in grams consumed at all meals regardless of ED (and FU size) When offered HED foods, kcal intake was greater compared to LED regardless of food unit size except for at dinner	No foods consumed outside laboratory. Daily energy intake higher on HED days vs. LED days	No difference in hunger and fullness ratings between meal conditions of varying ED	Food unit size and energy density measured in this study
Gall et al. 1998. n=82 control n=62 enriched all recruited from medical elderly care and orthopaedic wards	Control group received regular hospital food. Enriched group received the same meals enriched with natural ingredients (double cream, skimmed milk powder) and snacks (cake, sandwich)	Comparison between two groups; control receiving normal diet and intervention group receiving enriched meals	Not measured	Daily energy intake significantly higher with enrichment ($p<0.001$) (reported as energy deficit in control group significantly higher than enriched group)	Not measured	Despite the efficiency of enrichment for improving daily energy intakes, wastage was high (with energy intakes representing just 25 % of what was offered)
Odlund Olin et al. 2003. n=35 NHR (n= 18 control group, n= 17 experimental group)	Control group received meals with 1600 kcal/day whereas the enriched group received the same meals enriched with natural ingredients providing 2100 kcal/day.	Comparison between two groups; control receiving normal diet and intervention group receiving enriched meals	Not measured	Daily energy intake significantly higher with enrichment ($p=0.001$)	Not measured	
Smoliner et al. 2008 NHR n=22 intervention, n= 30 control	Normal food for control group. Intervention group received same meal with rapeseed oil, protein powder and heavy cream	12 week intervention measuring energy intakes and functional status in two groups of NHR	Not measured	No difference in daily energy intake with enrichment	Not measured	Provision of snacks not effective for improving energy intakes

1.6.3 Influence of enrichment of texture modified meals on eating behaviour

Concerns exist surrounding the success of texture modification, and/or the energy enrichment of these meals for improving energy intakes. These include the impact that these alterations may have on appetite responses and subsequent food intakes. An appetitive-suppressive effect as a result of these alterations would be undesirable, potentially negating any benefit of both texture modification; which aims to facilitate safe food consumption, and enrichment; which aims to enhance the energy content of the meal, therefore increasing the opportunity for the individual to consume their required intakes.

Specific concerns surrounding the initiation of potential appetitive-suppressive effects which may occur due to these alterations include; the initiation of early satiation (*i.e.* reduced within meal food intakes). Further there is the potential of a reduction in the motivation to eat (post-ingestion) and prolonged satiety; which can lead to longer between meal intervals which may impact on total daily energy intake. Finally, subsequent energy compensation may occur resulting in individuals altering their subsequent intakes based on the energy consumed previously which may (if reduced) negate any additional energy consumed through the strategy of energy enrichment.

This review has demonstrated that there is insufficient evidence regarding the effectiveness of enriching a TMD as a strategy to improve intakes, as was previously highlighted in policy (SIGN 119 2010). In order to develop strategies to maximise intakes in vulnerable individuals, particularly those requiring a TMD, it is necessary

to investigate the influence of both texture and energy density on appetite and eating behaviour (satiation and satiety).

Despite the evidence (albeit scarce) suggesting enrichment to be a potentially effective strategy there are a number of questions yet to be addressed, using well controlled study designs. For example, it is unknown if increasing the energy density of a texture modified meal results in greater energy intakes at a meal occasion. It is also not clear what impact provision of this energy dense meal may have on subsequent intakes, *i.e.* if compensatory behaviour takes place. It is also not known what levels meals should be enriched to in order to maximise the opportunity to meet energy requirements without impacting on longer term satiety.

Whilst the potential application of the current study includes those who may have health complications (hence the reason for the therapeutic dietary prescription), in order to control for disease state which can severely impact on appetite and food intakes (Stanga 2009), this study should be conducted in healthy individuals initially. In fact studies investigating appetite should first be conducted in healthy individuals (Stubbs and Elia 2001) to eliminate confounding effect of disease on appetite and food intakes.

1.7 Aims and objectives

Aims

The aim of this research is to investigate the effect of texture modification, and/or the efficacy of increasing the energy density of a standard meal developed to meet the

dietary coding criteria for a hospitalised, ‘nutritionally vulnerable’ adult (Scottish Government 2008) on appetite parameters and energy intakes in a healthy adult population.

Objectives:

- To assess the effect of texture modification (“Texture C” (“thick puree”) (BDA 2012a)) on food (g) and energy (kcal) intakes, within a meal sitting (to measure satiation) and over 24 hours (to measure satiety)
- To assess the effect of texture modification (“Texture C” (“thick puree”) (BDA 2012a)) on appetite (VAS ratings), within a meal sitting (period of 60 minutes)
- To assess the effect of providing an “energy dense” meal (Scottish Government 2008), versus a “standard energy” version of this meal (Scottish Government 2008) on food intake within a meal sitting (to measure satiation), and over 24 hours (to measure satiety and possible energy compensation).
- To assess the effect of providing an “energy dense” meal, suitable for provision in hospitals (Scottish Government 2008), versus a “standard energy” version of this meal on appetite ratings (VAS responses), within a meal sitting (period of 60 minutes).

Research hypothesis

It is hypothesised that altering a meal to represent one suitable for provision as part of a TMD would result in reduced food (g) and energy (kcal) intakes; however that subsequent enrichment of this TMD meal would result in increased energy intakes at a single eating occasion. It is unknown whether individuals would compensate by reducing energy intakes at eating occasions later in the day.

Chapter 2:

Development of study design, test meals and research protocol

2.1 Development of study design and research protocols:

It is clear and already presented in chapter 1 that there are a number of gaps in the literature supporting food based strategies for the nutritional management of both malnutrition and dysphagia. In fact, the lack of studies assessing food based strategies to manage these conditions is rather alarming. Evidence supporting the enrichment of texture modified diets as a strategy to promote energy intakes is particularly lacking. Despite this, as outlined previously (chapter 1, section 1.2.1) where possible, “food first” approaches, (including provision of texture modified diets, in dysphagia management (BDA 2012a)), underpin dietetic practice worldwide (NICE (UK) 2006; Department of Health and Children (Ireland) 2009; New South Wales Policy Directive: Nutrition care (Australia) 2011; Cichero et al. (2013)). To support this however, more studies are needed to build the evidence base surrounding food based strategies for safely meeting nutritional requirements. This particular study cannot address all of the uncertainties surrounding the nutritional management of malnutrition and dysphagia, and instead has sought to address one key aspect; energy enrichment in texture modified diets.

Experimental studies conducted in healthy individuals (discussed in chapter 1, section 1.6.2) investigating the alteration of energy density on eating behaviour tend to be conducted with the primary aim being to reduce energy intakes for obesity

management strategies (Bell et al. 1997; Rolls et al. 2004; Ello-Martin et al. 2007; Roe et al. 2011). This is the opposite of what this research study aimed to evaluate, that is; altering the energy density to promote energy intakes.

Studies in the clinical setting investigating enrichment of standard texture diets (Gall et al. 1998; Odlund Olin et al. 1996; 2003; Smoliner et al. 2008) to promote energy intakes suggest its potential for the nutritional management of malnutrition. However these studies were largely cohort studies (Gall et al. 1998; Smoliner et al. 2008), therefore an array of confounding factors relating to individual eating behaviours may be introduced. The fact that these studies were poorly controlled implies that findings cannot clearly be attributed to the energy density of the meals provided. Further, the disease state which is known to impact on appetite (discussed in chapter 1, sections 1.5 and 1.5.1) (Hill 1992; Richardson and Davidson 2003) of the patients in which the studies were conducted will likely have impacted on the findings to an unquantifiable degree.

Following a crossover study design can control for the additional impact incurred by individual eating behaviour and individual disease state (once stable over the testing period). However these designs can be difficult to conduct in the clinical setting, not least because ethically the treatment of the patient is the first priority. In some cases, more extreme clinical presentations make it difficult to conduct the lengthy assessments required for research (Patel et al. 2003). For crossover studies to be effectively controlled, the sample needs to be in similar states across each exposure, thus the exposures cannot have a lasting effect on the individual (Sibbald and Robberts 1998).

These aforementioned studies assessing energy enrichment for improving intakes in the clinical setting were further confounded by additional design issues. For example; in the study by Gall et al. (1998) different foods were offered amongst the enriched and unenriched meals. Using different test foods also introduce differences in macronutrient content, fibre content, palatability, taste, volume, all which impact on eating behaviour (Benelem 2009) and are discussed in detail, section 2.1.2. Also for the higher energy dense conditions, often additional snacks were provided (Odlund Olin et al. 2003; Smoliner et al. 2008) which increases the number of meal occasions for that group (high energy density group) further increasing the opportunity to consume additional energy compared to the low energy density group. Thus it is not clear if it is the energy density of the meals that impact on intakes, or the increased frequency of eating occasions.

As these studies only evaluated standard texture meals it is unknown if enrichment will be beneficial for improving short term energy intakes in meals that are texture modified in line with current National Guidelines followed in the United Kingdom (BDA 2012a), and this therefore warrants specific investigation. To accurately evaluate the impact of altering the energy density of these therapeutic meals, a randomised controlled study is needed. Such a study needs to consider the impact of both texture and energy density alterations, individually and collectively.

In order to design this research study, literature from experimental and clinical research as well as information from current policies and guidelines was consulted. To successfully meet the research aims and objectives it was necessary that standard protocols for conducting experimental research into eating behaviour were followed. However to ensure that the findings of the study had relevance to practice and to

allow potential application (clinical and community settings) it was important to ensure that where possible, the protocols and study design remained in line with the guidelines in place for food provision in these settings (chapter 1, sections 1.2 and 1.4). Figure 2.1 demonstrates an overview of the synthesis of information and literature that was consulted to inform the study design and research methodology, which will be explained in detail in subsequent sections.

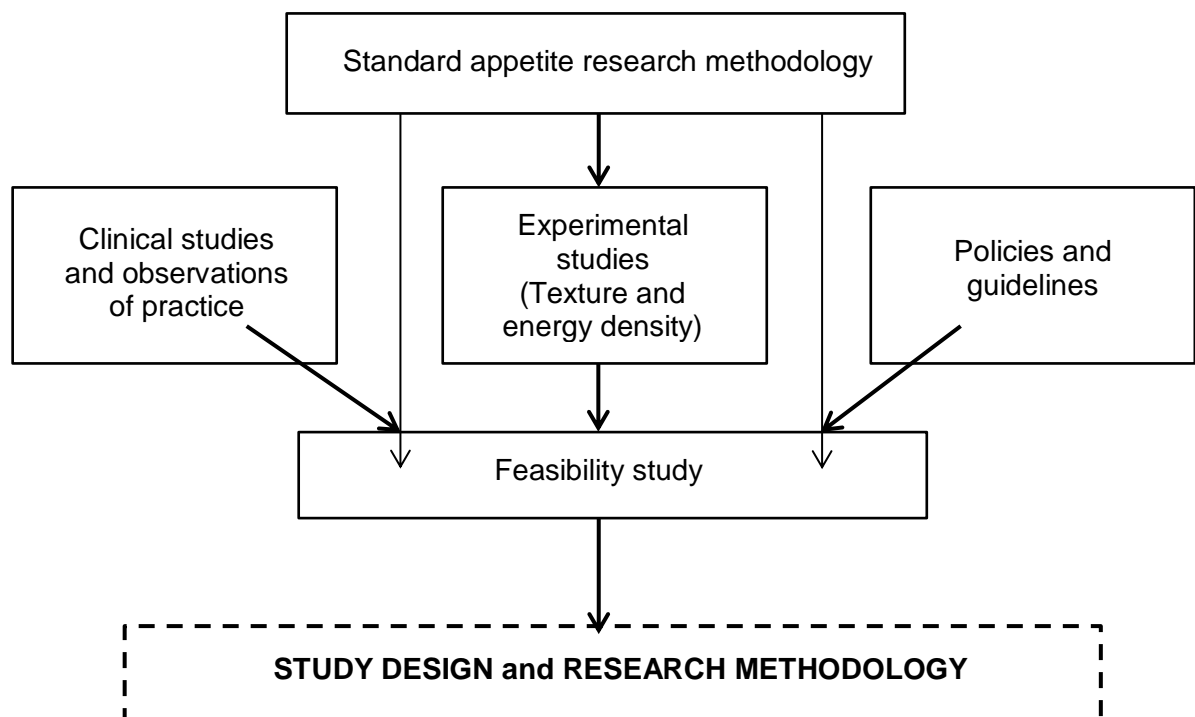


Figure 2.1: An overview of the synthesis of literature and policies to develop the research study design and methodology.

2.1.1 Standard appetite assessment methodology:

First and foremost, the current study was an experimental appetite assessment study and by its nature required the study design to follow standard research methodology

in this field (Allison and Baskin 2010; Blundell et al. 2010). It is however complicated by the fact that total energy intake is driven by exogenous and endogenous factors as is evident by the fact that individuals consume food even in the absence of hunger. This is due to external influences such as advertising and increased availability and high palatability of food, thus adding to the complexity of assessing food consumption behaviour (Table 2.1). Therefore when designing appetite assessment studies, consideration must be made to the many potential confounders incurred within food based appetite studies and how these may be specifically controlled.

Appetite studies are therefore generally conducted in the laboratory setting in order to attempt to control for any environmental factors that may influence eating behaviour (Benelem 2009). Arguably studies in these artificial environments may lack external validity. After all it is very difficult to measure habitual dietary intake, mainly because the intake of food is altered by the experiment undertaken to measure it (Dulloo and Schutz 2011). However laboratory based studies can be used as preliminary studies to enable the development of concepts and provide useful insight into how alterations in food or macronutrient characteristics can affect eating behaviour. After these have been established within a controlled environment, they may be evaluated for applications outside the laboratory setting.

In the laboratory setting, satiation is frequently measured by allowing subjects to consume food ad libitum, and measuring the quantity (g) consumed until satiation (*i.e.* meal termination) is reached compared to a control food (Allison and Baskin 2009). In real life settings, meal termination may be dictated by environmental cues such as portion size. In an institutional setting, for example a hospital or care home,

portion size is largely determined by the tight catering specifications and recipes developed by catering staff and dietitians in order to meet nutrient requirements, within a budget. Therefore the opportunity to consume more than is initially requested may not always be possible.

Although most catering departments offer a range of portions to suit the patients' preferences, often catering departments require patients to order their meals in advance of the mealtime (Audit Scotland 2006). This may be as much as 24 hours before the meal occasion (Royal Bournemouth and Christchurch Hospitals NHS Trust 2014) in which case patients' appetites may differ between these times (*i.e.* time of ordering and time of consumption). This may result in a discrepancy between the amount of food required to meet satiation, and the amount that was pre-ordered, leading to inadequate food intakes, or excessive plate wastage.

Satiety, (*i.e.* the period of time until the next eating occasion) can be measured using recorded feelings of appetite and/or measuring food intake directly (de Graaf et al. 2004). The preload design is the most commonly used study design for assessing satiety in humans, and is most useful for assessing short term effects of manipulations on food intake (Blundell et al. 2010). This design follows a protocol where subjects are fed a fixed quantity of a food (or test meal) referred to as a "preload" followed by the measurement of subsequent intake and/or subjective motivation to eat.

Measurement of subsequent intake may be directly measured by assessing intake from a buffet style meal presented after a pre-determined period (Allison and Baskin 2009). Being presented with a buffet may itself influence eating behaviour since it is

documented that being exposed to a greater variety of food promotes energy intakes (Stubbs et al. 2001; Norton et al. 2006; Brondel et al. 2009). Also a free-selection buffet, containing a variety of foods varying in palatability is an unreliable way of measuring preferences for particular macronutrients, and may in fact reflect the subjective hedonic properties of the foods offered. This method will therefore reveal very little about the specific determinants of food selection (Blundell et al. 2010).

Alternatively, post preload food intakes could be measured indirectly by asking participants to record subsequent intake using valid dietary recording methods (Farah et al. 2011; Pedersen et al. 2013). The latter, conducted outside the controlled laboratory setting may yield findings that can also be more easily extrapolated to free living populations. This method may provide more indicative impact of the preloads on subsequent eating behaviour as participants will not be confined to choose food from a fixed buffet, or be confounded by the impact that exposure to a variety of foods has on food intakes.

To measure subjective appetite sensations visual analogue scales (VAS), originally used in the study of pain ratings (Kanda et al. 2002) are used. When used appropriately, subjective ratings have been shown to be valid, reproducible, and even predictive of meal initiation and food intake (Stubbs et al. 2000). VAS are an extremely useful tool to give insight into eating behaviour, by providing quantifiable objective measurements which are translated from subjective sensations (Allison and Baskin 2009). As there are various factors driving the motivation to eat, these ratings can disclose more information than just measuring food intake alone. There is however some concern that the association between the VAS ratings and food intake

are modest (Mattes et al. 2005) and therefore arguably these may be best used in conjunction with an objective measurement of food intake.

As outlined earlier (chapter 1, section 1.5.1), potential biomarkers such as CCK, GLP-1, and ghrelin may be used as indications of satiety. These markers have however been criticised for poor feasibility and sensitivity (De Graaf 2004), factors which are vital if to be considered valid markers (Diplock et al. 1999). Their validity for assessing appetite and predicting food intake has also not adequately been demonstrated. Additionally, these measures are often costly and invasive, and therefore may limit recruitment. CCK has been proposed as a potential biomarker for measuring appetite since this hormone has an important role leading to satiation. A concern however is the technical difficulty of its quantitative assessment in the blood, due to its low plasma concentrations, extensive molecular heterogeneity and close homology to gastrin (Rehfeld 1998). These factors suggest that in fact use of this as a biomarker for assessing appetite is not suitable.

GLP-1 also may be used to measure satiation as it is released in response to nutrients, stimulating insulin and inhibiting glucagon (Harrold 2012). GLP-1 measures are feasible, reproducible, valid, sensitive and specific (de Graaf et al. 2004). However, whilst it can be measured feasibly and specifically (in blood), there is little known about the effect different foods may have on GLP-1 production, therefore more work is needed (de Graaf et al. 2004).

Ghrelin may also act as a biomarker for satiety as there appears to be a close relationship between ghrelin concentrations and appetite (Wren et al. 2001), where

high circulating ghrelin results in hunger and subsequently the initiation of food consumption (Dulloo and Schutz, 2011 (chapter 1, section 1.5.1)).

Whilst it seems promising that there may be biomarkers suitable for assessing appetite, more work needs to be carried out to indicate a clear picture. Instead of being used to quantitatively measure appetite, ghrelin, CCK and GLP-1 may be useful indicators to help to understand the mechanisms by which nutrients and meal components may act on food intake. It is important to consider that the level, extent and changes in biomarkers cannot be quantitatively related to satiety (Delzenne et al. 2010) therefore their interpretation must be made cautiously. After all, appetite is modulated by the integration of all of these incretion responses (chapter 1, Figure 1.2) and in the main, appetite studies tend to examine their release in isolation of one another.

The modulation of appetite is further influenced by an adaptive process as a result of long term energy intake and expenditure, for example adaptations in leptin and insulin responses (chapter 1, section 1.5.1). Thus assessing the quantitative release of these hormones may not be directly translated to feelings of satiety. Further, with specific context to the current study, it is not clear if physical alterations made to foods (*i.e.* texture modification) will impact on these biomarkers if macronutrient content is matched. A study by Zijlstra et al. (2009) demonstrated this by the fact that no difference in postprandial responses of ghrelin, CCK and GLP-1 were found with consumption of a liquid chocolate drink or semi-solid chocolate drink, despite the fact that satiation was reached faster with consumption of the semi-solid drink.

It is also important to be aware that appetite is driven not just by endogenous factors, but also by exogenous factors such as food availability and marketing. These biomarkers cannot replace the appreciation of different sensations of motivation to eat (*i.e.* hunger, fullness, and desire to eat) which can be assessed using validated scales (Delzenne et al. 2010). Therefore the use of food intake and subjective appetite responses are currently the most suitable measures of eating behaviour, and by using experimental situations, allows some control of potential confounders typically encountered (Table 2.1).

2.1.1.1 Implications for main study:

Since the use of VAS to assess appetite sensations, in conjunction with the direct measurement of food intake are considered the gold standard for measuring the effects of food properties on appetite (Allison and Baskin 2009; Blundell et al. 2010) these formed the foundation of the research protocol (described in chapter 3) for this research study. As interpretations of the questions asked on a VAS are open to individual interpretation, a within-study design was followed to control for inter-individual variation allowing the interpretation of data to be representative of the study manipulation rather than the individual variation.

To allow a greater appreciation of the impact of the test meals on eating behaviour and to assess how the different test meals impact on subsequent intakes (*i.e.* post-test meal), the participants were not confined to a laboratory buffet for assessing satiety. Instead subjects were required to continue with their day in the usual fashion whilst (as accurately as possible) recording all dietary intakes.

2.1.2 Experimental evidence:

The satiety cascade proposed by Blundell et al. (1987) demonstrates the factors that influence satiation and satiety over time, beginning when a food is seen and consumed and continues as it enters the gastrointestinal tract, where it is digested and absorbed (chapter 1, Figure 1.2). A number of factors can affect appetite and the regulation of food intake, even occurring outside of an eating occasion, potentially posing as confounders in appetite research. As well as the varying behavioural factors that may impact on food intake, both satiation and satiety can vary in intensity and duration depending on the speed and strength of the physiological signals, and the nature of the food itself (Allison and Baskin 2009). Thus, potential confounders must be identified and addressed when designing these types of studies.

Table 2.1 outlines key experimental evidence which surrounds general confounders which may be encountered in appetite studies, and how they may be controlled for when designing appetite and eating behaviour based research studies. These potential confounders were addressed with respect to the implications for the current study's design and protocols adopted (section 2.1.2.1).

Table 2.1 Overview of confounders encountered in appetite research and their potential impact on appetite study designs

Confounder	Evidence	Impact on appetite studies (i.e. not specific to the current research design)
Physiological		
Bodyweight	<p>-Obese and lean individuals may differ in their nutrient requirements.</p> <p>-Obesity may be caused by a genetic mutation in the leptin gene which will disrupt satiety signals (Gibson et al. 2004).</p> <p>-Obese individuals may also have greater stomach capacities compared to lean individuals (Kim et al. 2001)</p> <p>-Alterations in satiety signals may be observed in obese individuals, e.g. higher ghrelin levels (English et al. 2002) and lower PYY (Batterham et al. 2003) and GLP-1 (Ranganath et al. 1996) have been observed in obese individuals.</p> <p>-No studies evaluating the regulation of eating behaviour in healthy underweight</p> <p>-High circulating concentrations of ghrelin observed in those diagnosed with anorexia nervosa (Germain et al. 2010).</p>	<p>Studies should group by body weight status to avoid confounding the findings relating to eating behaviour. It should be considered when choosing the study sample, what the potential application of the study findings may be and therefore recruit a suitable, representative group.</p>
Age	<p><i>With advancing age:</i></p> <p>-Appetite declines (Morley, 1997),</p> <p>-Reduced capacity to correctly compensate for energy intakes (Rolls et al. 1995; Appleton 2011).</p> <p>-Greater sensitivity to CCK (the satiety associated hormone) (Wren, 2008)</p> <p>-Decline in sensory specific satiety (SSS) (Rolls and McDermott, 1991)</p>	<p>As advancing age can affect eating behaviours, appetite studies may recruit a sample of a particular age group.</p>
Gender	<p>Men generally require a greater energy intake due to heavier weight status and greater lean mass resulting in a higher basal metabolic rate (BMR).</p> <p>-Menstrual cycle may cause fluctuation in energy intakes throughout the cycle (Dyer and Blundell, 1997). Increases in food cravings can occur particularly in the late luteal phase of the menstrual cycle (Mc Vay et al. 2011). However a follow up study (Mc Vay et al. 2012) found no difference in food preferences or cravings for high fat or high sugar foods regardless of menstrual phase (late follicular or late luteal phases).</p>	<p>The phase of the menstrual cycle may not impact on eating behaviour and food choices as previously thought. Therefore, as concise evidence surrounding the influence of the menstrual cycle on human energy balance is still largely uncertain it is often ignored in human appetite studies (Buffenstein et al. 1995).</p>

Confounder	Evidence	Impact on general appetite studies
Disease state and medications	Disease and medications may: -Activate the inflammatory response altering metabolic requirements (Richardson and Davidson, 2003), -Impair absorption of nutrients (Stanga, 2009) -Change appetite signals and motivation to eat (Nguyen et al. 2007)	Researchers generally exclude these individuals to minimise confounders, unless of course the outcomes of individuals with a particular disease or medical prescription are of interest.
Behavioural		
Dietary restraint	Dietary restraint is defined as <i>the “cognitively mediated effort an individual makes to combat the urge to eat and restrict food intake in order to control body weight”</i> (Stunkard and Messick, 1985). Women (mean age 20.8 +/- 0.8 years) who score high on measures of dietary restraint develop abnormal eating patterns characterised by periods of self-restriction combined with periodic overeating (Chambers and Yeomans, 2011).	A validated questionnaire (TFEQ discussed in chapter 3) developed by Stunkard and Messick (1985) measures dimensions of eating behaviours including dietary restraint. Those found to be exhibiting dietary restraint may be excluded from appetite studies, or often grouped based on the level of restraint.
Habitual diet	A huge array of confounders may influence eating behaviour (promote or inhibit intakes) outside the controlled environment. For example: Accessibility of foods (Chandon and Wansink, 2012) price of foods (French 2003), Palatability of foods (Erlanson-Albertsson, 2005)	Control of a diet before a study commences may be important to ensure subjects are in energy balance.
Alcohol intake	-Alcohol may stimulate appetite (Hetherington et al. 2001). -Energy intakes at a test meal following a randomised order of four preloads (alcohol (30.6g), no alcohol no energy (non-alcoholic beverage), no alcohol with energy (45.4 g CHO), or water) did not differ, although intake following the alcohol preload tended to be slightly lower (not significantly) compared to the other preloads (Poppitt et al. 1996)	Subjects may be asked to refrain from alcohol on the day prior to, and on the test day.
Physical activity	-Physical activity may influence appetite and food intake -Subjective average appetite and prospective food consumption scores increased after physical activity in boys (Bellissimo et al. 2007).	Subjects may be asked to refrain from strenuous exercise on the day prior to the test day in order to standardise the test conditions.

Prior knowledge about the test foods	Expected satiety has been shown to affect appetite responses (Brunstrom et al. 2011).	Subjects must be unaware of the alterations made to the meals prior to the test meal to avoid altering behaviour prior to the session.
Confounder	Evidence	Impact on general appetite studies (<i>i.e.</i> not specific to the current research design)
Physical properties of foods		
Macronutrient composition	There is a hierarchy of satiety effect whereby protein > carbohydrate > fat (Stubbs and Elia 2001; Ryan et al. 2003; Benelem 2009). The impact of macronutrient composition warrants further discussion (section 1.2.1)	Match macronutrient compositions in appetite studies where possible (unless variable of interest)
Fibre content	High fibre content can impact on satiety by; Delaying gastric emptying, form gels in the stomach (soluble fibre) Increased mastication (Salas-Salvado et al. 2006) Viscous mouthfeel (Mattes and Rothacker, 2001). Absorb water leading to increased gastric distention (Kristensen and Georg Jensen, 2011). Other considerations with respect to fibre on satiety include the source, extraction procedure and processing which can affect the physico-chemical properties of the fibre (Kristensen and Georg Jensen, 2011).	It is important to ensure that the fibre content remains constant in appetite based studies (unless this is the variable you are investigating). The source, extraction procedure and type of fibre should also remain constant.
Palatability	The appearance and palatability of foods determine the magnitude of voluntary nutritional intake (Blundell and Stubbs, 1999). Repeatedly demonstrated that the palatability of a food has a positive effect on the amount eaten (de Graaf et al. 1999), and may even override other mechanisms of food intake regulation (Rolls, 2007).	Measuring and maintaining palatability (where possible) across test meals is important in appetite studies.
Portion size and volume	The volume of a product can affect appetite and intake by several means including; cognitive (Brunstrom et al. 2010), sensory (<i>i.e.</i> SSS) and physiological (Phillips and Powley, 1996) mechanisms (chapter 1, section 1.5.).	Match volumes and portion sizes in appetite studies where possible (unless variable of interest)

During the design of the current study, recruitment of test subjects and the choice and design of the test meals used, potential confounders were identified and addressed. A strength of using a within-subject study design was that this not only limits the inter-individual differences observed with VAS ratings between conditions, but essentially each individual acts as their own control thereby reducing the impact of other inter-individual factors (physiological and behavioural) which may have been introduced.

In some cases, for example the clinical setting, it may not be as feasible to conduct a within-subject crossover design for appetite studies. By their nature crossover studies can take a long time to complete (depending on the number of variables and duration of each intervention) and patients may not be able to complete the study due to undergoing treatment, changes in health status, discharge from hospital, or even death. Any fluctuations in the characteristics of a participant during the study period would result in within-patient variation. Thus the comparison of treatments would not be fair (Cochrane Collaboration 2002).

Whilst a repeated measures within-subject design controls for inter-individual confounders (*i.e.* individual eating behaviours), it is still possible to evaluate the resulting impact that alterations in the physical properties of foods have on eating behaviour using this design. For example, in the current study it was possible to evaluate the impact of alterations of texture and energy density on eating behaviour, whilst using a within-subject design. To clearly relate the impact of the specific alterations (*i.e.* texture and/ or energy density) however, all other properties of the food (outside of the alterations of interest) needed to be matched across the test foods.

Both texture and energy density, and their general impact on appetite have already been extensively discussed (chapter 1, section 1.6). Other physical properties, that can impact on eating behaviour (thus also potentially acting as confounders in general appetite studies), such as; macronutrient content, volume, fibre content and palatability have also been summarised (Table 2.1).

The macronutrient composition of meals is a well-established factor for influencing eating behaviour (Table 2.1) and it is therefore important that this was considered in the development of the study design (including the test meals used). There is a hierarchy of satiety effect whereby protein > carbohydrate > fat (Stubbs and Elia 2001; Ryan et al. 2003; Benelem 2009). Protein has a faster oxidation rate than carbohydrate, and stimulates a greater dietary induced thermogenesis (DIT) which has been related to enhanced satiety (Bertenshaw et al. 2009). Some researchers claim that the amino acid profile or type of protein can alter satiety (Veldhorst et al. 2008). However earlier studies that have researched the effects of different types of protein (egg albumin, casein, gelatin, soy protein, pea protein and wheat gluten) on satiety (Lang et al. 1998) have found no significant difference in their effects on appetite. These proteins were co-ingested with other macronutrients which may affect the rate of gastric emptying thereby blurring the effect of the individual protein source.

The effect of a carbohydrate on satiety depends on the form of the carbohydrate and other aspects of the food (e.g. fibre content and type, and glycaemic index). It has however been suggested that energy adjustment following protein and carbohydrate preloads is actually similar, but dissociates after time (>120 min) with the inducing

effect on satiety remaining stronger with protein (Reid and Hetherington 1997). Considering this, it is important to monitor eating behaviour for periods longer than 120 mins in order to evaluate eating behaviour after which the influences of the different macronutrients may differ. Alternatively, ensuring the protein and carbohydrate contents remain the same between the meals that are being investigated will control for the dissociation in satiety effect.

Fat has been shown to be the least satiating macronutrient (Rolls et al. 1988; Westerterp-Plantenga 2004) but is also known to be extremely palatable (Blundell and MacDiarmid, 1997; French and Cecil 2001) which could lead to increased intakes. Physiologically, fat has been shown to be less effective than carbohydrate or protein at suppressing ghrelin (Monteleone et al. 2003; Overduin et al. 2005). It is thought that this factor, along with the delayed gastric emptying observed with fat intake is a potential mechanism to explain its weaker effects on satiety (Little et al. 2007).

2.1.2.1 Implications for main study:

Key evidence from experimental studies identifying potential confounders encountered in appetite studies informed the methodology for the current study as outlined below. Full description of the overall methodology adopted in the study, considering controls put in place to minimise these confounders is described in chapter 3. Based on standard appetite assessment methodology a within-subject design was adopted, which would control for inter-individual factors which may be

introduced, as each subject acted as their own control. Although this method minimises inter-individual factors relating to eating behaviour, it was recognised as important to recruit a sample that can be categorised in order to be able to draw comparisons with other studies.

As the potential applications of the study findings were not limited to one gender, both men and women were recruited with the within-subject design controlling for gender differences. Obese individuals ($\text{BMI} > 30 \text{ kg/m}^2$) display altered eating behaviour and therefore were not permitted in the study. Also considering the aim of the study; to increase energy intake, it is unlikely that obese individuals will be aiming to increase their energy intake and the results will therefore have more relevance to a non-obese population.

No literature was found that specifically investigates the regulation of eating behaviour in healthy adults with normal eating behaviour, who are classed as underweight ($\text{BMI} < 18.5 \text{ kg/m}^2$). It is known that those with anorexia nervosa have higher circulating ghrelin as a result of prolonged periods on starvation (Germain et al. 2010) and those with cachexia exhibit higher rates of basal energy expenditure (Tisdale 1997; Inui 2002). However it was thought that by including only healthy subjects with unrestrained eating behaviour that those exhibiting low weight status as a result of these conditions known to impact on the regulation of food intake would be also be eliminated within these exclusion criteria (*i.e.* ill, dieting or exercising dietary restraint). For that reason no lower BMI limit was enforced.

Considering the potential application of the findings of this study to inform hospital food provision in those requiring TMDs, an older adult sample would be more

relevant. However the need for a TMD is not limited to older adults, such that the current guidelines apply to both children and adults (BDA 2012a). This, coupled by the general lack of food based studies investigating strategies to manage malnutrition suggests that it is justified to conduct this study in a sample of varying ages. A within-subject study design needed to be implemented to control for any inter-individual variations occurring as a result of including a range of ages.

To accurately detect the impact of texture and energy density alterations on eating behaviour, subjects recruited to this study were to exhibit normal eating behaviour. In the current study, normal eating behaviour was characterised by; not exhibiting dietary restraint and, not being confounded by disease or medications known to impact on appetite. All subjects were therefore screened using a validated tool testing for restrictive dietary behaviours (*i.e.* the restraint factor of the TFEQ, discussed in chapter 3) prior to commencing the appetite study. Exclusion of such individuals was important when assessing dietary modifications on appetite as restrained individuals less accurately respond to their feelings of appetite, and instead actively limit their food intake which is potentially followed by a period of binge eating (Chambers and Yeomans 2011).

It is evident that it is not just the energy content of a meal which can impact on eating behaviour, but also the macronutrient content (Stubbs and Elia 2001; Ryan et al. 2003; Benelem, 2009). As the current research study design fundamentally required differences in energy density, the macronutrient content of meals (varying by energy density) also differed. It was however important to maintain the macronutrient content as much as possible, therefore controlling the overall

macronutrient content of the meals studied was central to the development of the test meals (section 2.2).

As protein has a particularly high satiating effect (Stubbs and Elia, 2001) this needed to be maintained across the meals. Carbohydrates, in particular fibre can also impact on eating behaviour (Table 2.1) therefore also needed to be maintained across test meals. Considering these points; fat was identified as a potentially useful macronutrient for enrichment in the current study. This macronutrient was the least likely to impact on satiation at the test meal (Stubbs and Elia 2001; Ryan et al. 2003; Benelem 2009), and subsequently induce prolonged satiety. Therefore fat was least likely to reduce intakes at the test meal and least likely to reduce subsequent intakes after the testing session and thus allows for overall increased energy intakes.

In this particular study design, test meals were provided for consumption ad libitum therefore individuals portions consumed were decided by the participant. This was intended as the portion consumed in fact denoted the satiating capacity of the meal. However when designing the test meal (section 2.2), the individual portion size of the meals which differed by texture and/or energy density were equal across meals. This was important to ensure as portion size can impact on eating behaviour (Phillips and Powley 2000; Brunstrom et al. 2010), thus introducing a potential confounder should these differ across meals.

This was a single blind study, where participants were not told what the alterations of the test meal were, and also were not told that their food intake at the test meal was being recorded. As the researcher developed and freshly produced the test meals a double blind study design was not possible in this case. As is standard procedure, at

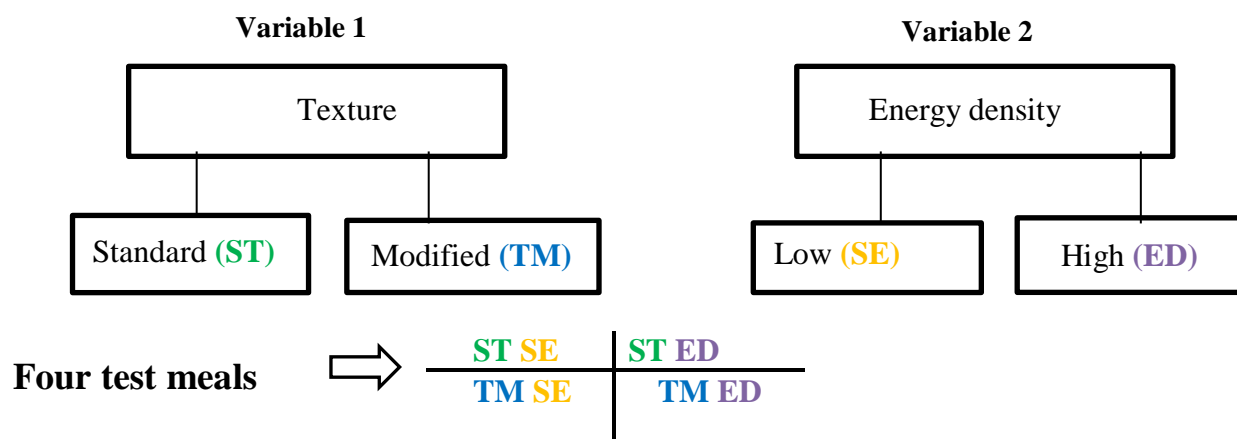
the testing sessions it was ensured that participants could not interact with each other, or gauge each other's quantity of food intake which may have altered eating behaviour. The test meals were served to each individual in a crossover design; therefore the order of the meal served was randomised to avoid any "order effect" from being introduced which may have confounded the results.

The test days were standardised as much as possible in order to specifically detect what impact the meal alterations had on eating behaviour. Due to its known potential to stimulate appetite (Hetherington et al. 2001; Gee 2006), alcohol consumption was prohibited prior to, and on each test day. Excessive physical activity, described as any exertions outside the activities of daily living (eating, bathing, dressing, toileting, and transferring, (Wiener et al. 1990)) was also avoided on these days in order to standardise the conditions between the test days. Subjects were also asked to standardise their food intake prior to consuming the test lunch in order to ensure similar states of energy intakes and desire to eat. This involved consuming a standard breakfast (decided by each participant, based on usual consumption), followed by a four hour period of fasting.

To accurately detect the impact of the test meal alterations on satiety, post-test meal food intake was to take place outside of the laboratory. This was to allow free choice of food intake over the remaining period of the day. Subjects were however required to document all food and drink consumed in diet diaries, so that the period of satiety and any evidence of energy compensation could later be determined.

2.1.3 Guidelines and policies

This study investigated two independent variables; (1) texture and, (2) energy density, both with two levels. Therefore a total of four test meals (Figure 2.2) were developed with either standard or altered texture and/or energy density.



ST SE: Standard texture, standard energy ST ED: standard texture, energy dense,
TM SE, texture modified, standard energy, TM ED: texture modified, energy dense

Figure 2.2: Overview of test meals necessary to fulfil research aims

The policies chosen to be followed for the development of the test meals were the “The National Descriptors for Texture Modification in Adults” (BDA 2012a) which aims to categorise foods and fluids based on different textures (nationally), and Food in Hospitals (Scottish Government 2008) which outlines good nutritional practice in the hospital setting (Scotland) with advice for “nutritionally well” and “nutritionally vulnerable” patients as well as recommendations for those requiring either an “energy dense” or “standard energy diet”. Whilst “*Food in Hospitals*” (Scottish Government, 2008) is specifically developed for use in Hospitals in Scotland, the

guidelines have been used as the basis for designing policies outside of Scotland (Agency for Clinical Innovation 2011; (New South Wales Australia); Welsh Government 2012).

These two policies have been discussed elsewhere (chapter 1, section 1.4); therefore only key information relating to the meal development will be included in this section. From “The National Descriptors for Texture Modification in Adults” (BDA 2012a), guidance for “Texture C”, “thick puree dysphagia diet” was followed as this is suitable for a range of individuals with a range of complications including those with difficulty masticating and manipulating food in the oral cavity, those with dentures and those with swallowing difficulties such as dysphagia. A full description of the “Texture C”, “thick puree dysphagia diet” can be seen in Table 2.2

Table 2.2: Description for a “Texture C” “*thick puree dysphagia*” diet

Texture C	<ul style="list-style-type: none"> ○ A food that has been pureed or has a puree texture. It does not require chewing ○ It is smooth throughout with no “bits”. It may be sieved to achieve this. ○ It may have a fine texture quality as long as the bolus remains cohesive in the mouth ○ It is moist ○ Any fluid in or on the food is as thick as the puree itself ○ There is no loose fluid that has separated off ○ The texture is not sticky in the mouth ○ It is not rubbery ○ No garnish
-----------	--

Source: BDA 2012a. “National descriptors for texture modified foods and fluids.”

From “*Food in Hospitals*” (Scottish Government 2008) the guidance regarding the essential criteria for the provision of nutrients for hospitalised adults was followed for both a “nutritionally well” (*i.e.* standard) and “nutritionally vulnerable” (*i.e.* energy dense) diet. This research was looking at one meal that could contribute to the overall diet and as set out in policy it is essential that the requirements for energy and protein are met at each individual meal occasion (Table 2.3). That is not to say that other nutrients are less important, and it is indeed imperative for overall health, and a successful recovery that all nutrient requirements are met.

However, with respect to provision of all other nutrients, policy does not present targets on a meal by meal basis but in fact as an average over the day (non starch polysaccharide (NSP), sodium, salt equivalent), or in the case with most nutrients, averaged over a week (total fat, saturated fat, carbohydrate, non-milk extrinsic sugars (NMES), vitamins A, D and C, calcium, potassium, magnesium, iron, zinc, vitamin B₁₂ and folate). Thus meeting targets for these were not specifically addressed during meal development in the current study. A full analysis relating to the nutritional content of the test meals was conducted after development however, and information regarding these nutrients has been presented (section 2.2, Table 2.8).

Table 2.3 Energy and protein requirement guidelines per standard and energy dense meal portion

	Energy per meal portion	Protein per meal portion
Standard	> 300 kcal	18 g
Energy Dense	> 500 kcal	18 g

Source: Scottish Government, 2008.

2.1.3.1 Implications for main study:

Current guidelines were followed when designing the test meals in order to build on current knowledge and also to keep the research relevant, potentially with real application. It was hoped that by developing meals which match currently followed guidelines that the meals could in theory be offered in practice (*i.e.* the clinical setting) or at least, be used to inform the development of meals that could be offered in practice.

As already discussed the policies followed were “*The National Descriptors for Texture Modification in Adults*” (BDA 2012a), and “*Food in Hospitals*” (Scottish Government 2008). Since those receiving a TMD report a decrease in food intakes (Wright et al. 2005; Bannerman and McDermott 2009) coupled with the added risk of nutritional dilution during the production of a TMD (Vigano et al. 2011), those receiving a TMD are at risk at being nutritionally vulnerable. Foods that are texture modified may therefore be enriched in practice in order to increase their energy density in an effort to increase energy intake (SIGN 119 2010). It was therefore justified to follow these guidelines (provision of a meal for nutritionally vulnerable within “*Food in Hospitals*” (Scottish Government 2008)) with respect to development of the TM meal to be used in this study.

Based on advice issued within these policies, the test meal was to be capable of being developed to match the requirements of a “Texture C” consistency, whilst being capable of matching a “standard energy” meal and also be successfully enriched to an “energy dense” meal. This had to be achieved without negatively impacting on the overall quality and acceptance of the meals, which would limit intakes. Maintaining

the aesthetics of the meals was central to ensure adequate consumption, and was therefore fundamental to the success of the intervention.

Some foods are unsuitable for provision as part of a “Texture C” diet and therefore were not suitable for inclusion with the test meal recipes. Such foods include fruit and vegetable skins (including beans), stringy, fibrous foods (celery), crunchy foods (toast, crisps), crumbly foods (crusts, dry biscuits), hard foods (boiled sweets, nuts, and dried fruits) and husks (sweetcorn) (BDA 2012a).

Aside from meeting the guidelines outlined in policy, the practicality of the meal was considered; the meal served had to facilitate practical completion of the testing session, in terms of management, ad libitum serving and nutritional analysis. A detailed description of the meal development, including rationale for meal choice can be found in section 2.2.

2.1.4 Observation of institutional catering/ food service

The confounders introduced by recruiting an infirm sample such as disease state, medications, physical activity levels and psychological state, dictated this research to be conducted in a controlled setting using healthy individuals. Further, the study design that was followed to meet the research aims would not have been safe or ethical to conduct in an unwell and/or dysphagic population. This was mainly due to the varying textures of the meals to be consumed to meet the research aims, but also due to the restrictions that were put on the study participants, such as fasting prior to the test meal occasion and not taking medications known to affect appetite. Providing a dysphagic individual or an individual in need of a TMD for mastication issues, with

a diet with a consistency that does not suit their dietary prescription potentially leads to a huge array of complications such as the inability to consume the food (contributing to malnutrition), aspiration and in some cases even death.

By following the guidance which outlines hospital food provision and also consideration of the key features of hospital food catering such as, time of day that the main meal is served, the type of meals typically served in the hospital setting, and remaining in line with the budget allocated for hospital food provision; the findings may be more readily applied in a clinical context. To gain a greater appreciation for what occurs in practice with respect to hospital food provision, a number of Scottish catering facilities were visited between March and August 2010. These included hospitals from different regions within Scotland (Tayside, Lothian, and Grampian), with different specialisms (care of the elderly, post-acute care and rehabilitation services, general medicine), which adopted different catering systems (cook- serve, cook- freeze, plated, and bulk). A central production unit was also visited which prepared cook-chill and cook-freeze meals (including those suitable for texture modified diets) to deliver to off-site hospital units. These visits included discussions with dietitians, catering managers, chefs and catering staff , gaining additional insight into the overall process of hospital food provision and the many challenges that exist when providing meals to a group with a vast range of complications and requirements (chapter 1, section 1.3.3).

Whilst visiting a catering department within a general medicine facility the researcher had the opportunity to oversee the total catering process from receiving orders to delivering meals to the wards (plated serving system in place). Of the facilities visited all sites producing meals for consumption on-site used the cook-

serve method of food production. All facilities followed the guidelines for food provision namely, Clinical Standards for Food Fluid and Nutritional Care (NHS QIS 2003), as discussed in chapter 1, section 1.3). These standards do not however issue specific guidance on the provision of nutrients, therefore recipes, and hence nutritional profiles of meals served varied between each site.

Some observations were made at the sites visited which could provide further insight into the overall difficulties, particularly with therapeutic dietary provision. In all sites visited there appeared to be a heavy reliance on proprietary products (e.g. ONS), particularly for provision of energy dense products as a means to increase overall energy intake. It is not disputed that these proprietary products certainly have their place within the hospital setting, for example for use during “out of hours” food provision or to supplement intakes between meals. However they should not be relied upon as a first choice for nutritional management, where other options such as additional assistance with eating and provision of energy/nutrient dense meals are available.

Two catering managers were specifically asked if any attempt had been made to enrich meals to increase the energy density using energy dense ingredients. Both individually replied that soups had been enriched using cream and butter, however patients seemed to consume less (g) and thus they assumed that it was not effective for improving food and energy intakes therefore this strategy was quickly abandoned. It should be emphasised that this strategy was not quantitatively or formally assessed. Also, in both cases it did not appear that trials into the development of these enriched soups were carried out suggesting that the level of enrichment and resulting impact on meal aesthetics was not properly assessed.

Perhaps it is the case that enrichment (type and amount) needs to be decided at the recipe development stage rather than at meal production stage. The current study will help to inform such practices.

An observation relating specifically to the preparation of texture modified meals was the apparent lack of understanding that some catering staff appeared to have with regards to the function of a TMD. This included the rationale for the prescription of a TMD and the importance of achieving consistent textures in line with what is prescribed. For example, on one occasion, during preparation of a batch of TMD meals, a catering staff member was observed to add a commercial thickener to the batch free-handed with no measurements. This likely resulted in the production of a meal that was not the intended texture or consistency, increasing the risk of poor consumption or aspiration. Alarming, the staff member disclosed that nutrients were being added, rather than a thickener, demonstrating a lack of awareness of the function of commercial thickeners in practice.

2.1.4.1 Implications for main study:

Considering the potential application of the findings of the current research study, key observations from institutional catering practices were included in the design of the study. The test meal in the study was served at lunch time to mimic the time of day that patients typically receive and consume their daily main meal. It is in fact advised that for hospital patients 25% of the energy should be provided at breakfast, 30% at lunch and 25% in the evening. The remaining 25% should be distributed over

the day in form of snacks (Van Bokhorst de van der Schueren and Norman, (on behalf of ESPEN) 2011).

With respect to meal design and development of the test meal was produced using familiar, accessible ingredients that would be suitable to provide on a hospital budget, whilst being a meal that is commonly consumed by the UK population. A comprehensive recipe was developed with standardised measurements and procedures to follow in order to facilitate compliance to recipes and ensure standard meal production throughout the study period.

The test meal was prepared following the cook-serve method mimicking the service provided by hospitals which have their own catering facilities on-site. Also, although in practice meals may be prepared and frozen following a cook-freeze method of production, it is unknown what impact freezing the test meal may have on the cohesiveness of the texture modified meal when defrosted. Both freezing and thawing can alter the content and distribution of water in meat (Leygonie et al. 2012), whilst the impact of freezing and thawing fruit and vegetables on texture is also well reported (Zhang et al. 2004; Chassengre-Berces et al. 2009; Goral and Kluza 2009; Rawson et al. 2012).

Figure 2.3 below displays an overview of the key design considerations (as detailed in previous sections; sections 2.1.1-2.1.4) learned from standard methodology, experimental evidence, policies and guidelines as well as observations of hospital catering services.

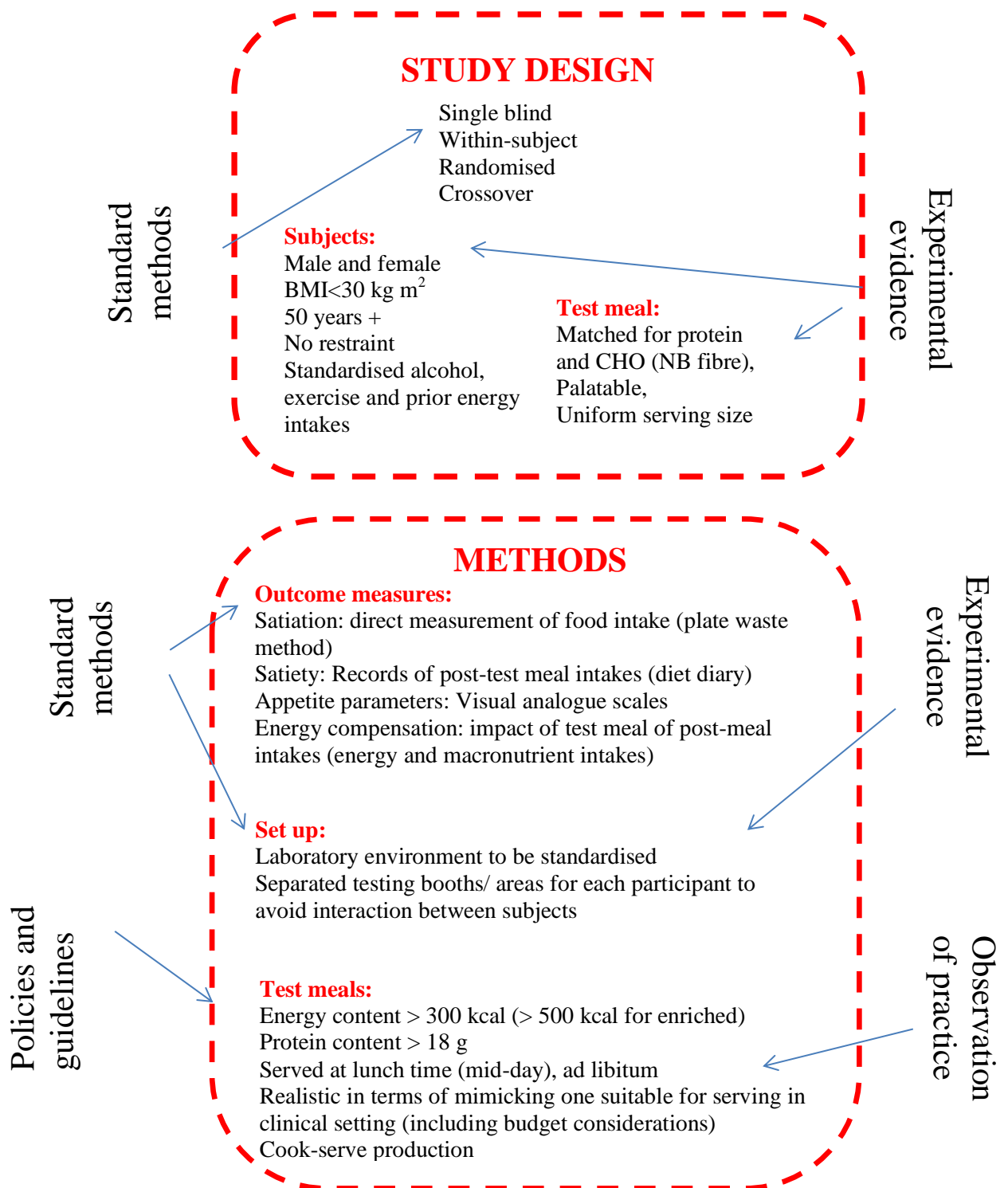


Figure 2.3: An overview of practice, policy and evidence/ literature used to develop research study design and methodology

2.2 Development of test meal

The meal chosen for use in this research was a potato topped beef based pie similar to a cottage pie, as it was thought to fit all of the necessary criteria, namely for; texture, energy density, practicality and application. Generally the unmodified cottage pie texture most closely represented that of a “Texture E” (“fork mashable”) diet which is suitable for serving to a wide number of members of the hospital and care home populations. The proportion of individuals requiring a soft, easy chew diet (of which both a “Texture E” and “Texture C” could be prescribed for) increases with advancing age for reasons such as difficulty with mastication, xerostomia which is a common side effect of medications (Mioche et al. 2004) and also the presence of dentures. Studies have demonstrated that oral health among the elderly is less than adequate (Lamy et al. 1999) and therefore a texture modified diet may help facilitate food consumption. A full description of the requirements of a “Texture E” diet can be seen in Appendix 1.

This meal; cottage pie, was also capable of being successfully modified to represent a “Texture C” diet. Usually, manipulating the texture of a food will visually alter the meal which could affect the cognitive perception of the meal and potentially inhibit intake. After all initial assessments of food are through vision (Blundell and Tremblay 1985, chapter 1, Figure 1.2). By using cottage pie as the test meal, it was possible to initially mask the extent of these textural alterations. This was because the mashed potato which typically tops a cottage pie naturally represents that of “Texture C” diet requirements. This resulted in the masking of the textural alterations made to the rest of the pie when the participants received the texture modified meals.

Thus cognitive adjustments based on the visual appearance of the meal were avoided, as all the test meals were presented identically.

In the hospital setting in Scotland, cottage pie is considered a composite dish, and guidance states that these dishes need to consist of a protein containing food, vegetables, and a starchy/ carbohydrate item (Scottish Government 2008). It was thought that this dish could be developed to match the energy and protein requirement guidelines for both standard and energy dense meal versions while following the requirements for composite dishes, and also for a TMD (Texture C) as stated above. The dish consisted of a potato topping, which is often used as a suitable vehicle for enrichment in NHS Trusts through the addition of energy dense ingredients, such as cream, butter and cheese (The Christie NHS Foundation Trust 2012; Norfolk and Norwich University Hospital NHS Foundation Trust 2013; Stockport NHS Foundation Trust 2013).

Cottage pie was also a meal that could be served ad libitum with minimal logistical issues thereby allowing the feeding sessions to run smoothly. The meal also offered application as it is a meal that is commonly offered and served in hospital and care home settings in Scotland whilst also being a meal that is generally acceptable and familiar to the experimental group. Before proceeding however, a basic cottage pie recipe was reviewed against the required information (texture, aesthetics and nutritional information) to ensure its' overall suitability.

The first four steps for recipe development in Food in Hospitals (Scottish Government 2008) were used as guidance. These steps include;

- Recipe review

- Recipe preparation
- Determination of recipe yield
- Determination of portion size

1) Recipe review:

The meal was firstly assessed for suitability for texture modification as modifying the texture of a food can require the addition of fluids in order to achieve the appropriate texture, often resulting in the dilution of nutrient density. After determining the level of fluid necessary for texture modification, the recipe for the standard texture meal version was then adjusted by incorporating this information thus minimising additional nutrient loss later (e.g. by dilution). Some ingredients do not blend successfully which can result in the incorrect final texture therefore this was assessed before final inclusion of ingredients was decided.

Policy (Scottish Government 2008) outlines that each ‘standard’ and ‘energy dense’ meal needs to contain at least 300 kcal and 500 kcal respectively, and that both meals need to contain at least 18 g of protein (Table 2.2). Nutritional analyses were conducted using the nutritional analysis programme; WinDiets (WinDiets, 2005: Robert Gordon University, Aberdeen UK.), “The Composition of Foods” (Food Standards Agency: McCance and Widdowson 2002), and nutritional information on the ingredient packaging entered into a specifically designed recipe nutritional spreadsheet (Microsoft Excel 2010). A number of combinations of the agreed ingredients were tried using the database in order to achieve the necessary nutrient profiles before the final recipe for the test meal was decided. When a combination that matched the guidelines was identified, this recipe was trialled on a mini scale and

assessed in terms of taste, palatability and subjective texture by the research team. This is similar to how products are developed in industry, in a pilot kitchen. It was important to consider that the alterations made did not adversely affect the palatability of the meal potentially affecting food intakes independently of the texture and energy density alterations. The acceptance of the meal was to be further assessed by individuals outside of the research team during a feasibility study which took place prior to the main study (section 2.3).

A summary of the issues encountered with texture modification and achieving the appropriate energy and protein profiles, as well as solutions put in place to rectify these issues can be seen in Table 2.4.

Table 2.4:
Issues encountered and solutions/modification made during initial test meal recipe trials

Basic recipe (per 3 portions)	Issue encountered	Solution	Final recipe (3 portions)
1 sprig of thyme	Did not blend	Omit	-
Handful of parsley	Did not blend	Omit	-
1/2 onion	Did not blend	Replace with onion powder	1 tsp. onion powder
450g minced beef	Protein content high	Reduce beef content	240g minced beef*
1.5 tbsp. Worcester sauce	-	-	19.5g
0.5 tsp. tomato puree	-	-	12g
200 ml chicken stock	Incorrect viscosity	Add gravy granules	12g gravy granules
1 tbsp. vegetable oil	-	-	0g*
700 g potato	Too much potato	Reduce quantity	480g
120 ml milk	Quantities need to match nutrient requirements for standard and energy dense meals	Quantities altered to meet nutrient requirements	60 ml semi skim milk*
55g butter			15g fat spread (60% fat)*
			Fat spread (75% fat) + double cream (energy dense meal only)*
			+ 70g carrots
			+ 30g mushrooms*

Quantities altered depending on meal type (ST or ED). Complete ingredient lists and recipes can be seen in Appendix 2 and 3 (a-d).

Thyme and parsley were omitted from the trial recipe as these did not blend successfully, resulting in a meal that is not cohesive, a property central to achieving a “Texture C” meal. After initial texture modification it was discovered that onion also did not suit texture modification due to its fibrous skin therefore it was decided that onion would not be included in the final recipe. Instead, it was replaced with onion powder in order to compensate for the loss of flavour from fresh onion, especially as thick, viscous meals are known to have a dulled detected flavour intensity compared to less viscous meals (Hollowood et al. 2002).

The quantity of beef was reduced as the initial protein content was considered to be high in terms of measuring the study outcomes, as protein is known to be highly satiating (Stubbs and Elia 2001; Ryan et al. 2003; Benelem 2009). It was therefore decided to keep this at a level that was close to the minimum recommended amount of protein (Scottish Government 2008 (Table 2.3)) in order to reduce the risk of inducing early satiation due to the high protein content whilst still meeting the national recommendations. Cost was also considered as beef can be quite expensive (~ £8.40/ kg lean (<12 % fat) beef, (mysupermarket, 2012)) therefore reducing the quantity to that suitable to meet the guidelines also reduced the cost of producing the test meal, which is an important consideration when considering application to a hospital setting, due to budget constraints (chapter 1, section 1.3.3).

Gravy granules were added to the recipe along with the chicken stock as the fluid component of the cottage pie was considered to be too thin to achieve the appropriate texture (“Texture C”) requirements and therefore needed to have its viscosity increased to yield the correct consistency for the texture modified meals.

Guidance outlined in Food in Hospitals (Scottish Government 2008) states that each meal should be served with a choice of at least two portions of vegetables (for those suitable for receiving a “healthy balanced diet”). Mushrooms and carrots were added to this composite dish in order to contribute to meeting the recommended “five portions of fruit/vegetables a day”. A full list of the ingredients used in the basic recipe can be seen in Appendix 2.

2) Recipe preparation:

Once the recipe had been developed to match the nutritional standards and texture modified guidelines, and was considered aesthetically acceptable (based on initial feedback from the researcher and supervisory team), the recipe needed to be standardised. Food in Hospitals (Scottish Government 2008) states that standardisation is essential to ensure consistent quality, consistent nutritional value, consistent budgetary control, and safe provision of therapeutic diets. Also, in order to achieve the research aims, it was essential that all the test meals were prepared to a standard recipe and protocol. All raw ingredient components and quantities were listed (including water and seasoning). Ingredient names were stated clearly along with the brand name, product type (fresh/powdered) and preparation technique (e.g. peeled, grated, minced, or diced). A descriptive list of the ingredients and brands used for the recipes can be seen within Appendix 2.

A standard method of production was also required. This included details of equipment and cooking times and temperatures to ensure consistency with the product produced. Full descriptions of the recipes and methods can be seen in

Appendix 3 (a-d). Photographs were also taken and documented to aid standard preparation (chapter 2, Figures 2.4-2.7).

3) Determination of recipe yield:

When the meal was prepared, the final weight was measured to determine the yield. Weight and nutrient losses are experienced with cooking therefore the method of test meal production was developed in order to minimise these losses. Methods adopted in order to minimise moisture losses included, covering the dish during cooking at all times to avoid moisture loss and also to allow the cooked meat mix to cool slightly before the lid was removed to allow serving to avoid moisture escaping as steam. The meat mix was also cooked over a low heat, as cooking on high heat would excessively denature the proteins (meat) which leads to excessive moisture losses (Damodaran 1996). Excessive moisture losses during cooking can reduce the quality (sensory and nutritional) of the meal.

4) Determination of portion size

The single portion size of the test meal was based on the quantities that would be offered in the hospital and care home setting, considering nutrition provision targets (Table 2.6). Policy states that the portion size should suit the patient group to whom it is being served therefore can vary greatly within the hospital setting. Despite this, it is essential that the portion served is appropriate for encouraging adequate nutrient intakes. The resulting individual portion size was 390 g which was deemed an acceptable serving size of the meal based on visual appearance on the serving plate. Further this portion was similar to the quantities of cottage pie portions provided in

other settings (Hospital Caterers Association recipe database (260 g) and Wiltshire Farm Foods texture modified cottage pie (430 g)) (Table 2.8). This portion size also enabled the adequate provision of energy and protein as dictated in policy (Table 2.3).

The research protocol adopted in this study (chapter 3) specified that participants were required to serve themselves a self-decided portion of the meal from an ad-libitum serving. For that reason, self-served and also consumed portion sizes were unlikely to be uniform among participants in this study design. As the test meal portion was developed to meet nutrient specifications outlined in policy (Scottish Government 2008, (Table 2.3)), these servings were then scaled up, to allow ad-libitum feeding. However the weight of product available for consumption was equal for all participants in order to ensure that all participants had the same opportunity to consume the maximum amount of product needed to reach satiation. All participants were presented with the same initial quantity of ad-libitum pie to avoid introducing bias based on the cognitive factors associated with portion size and intakes (Brunstrom et al. 2010).

2.2.1 Texture development

A key reason for choosing cottage pie as the test meal was the fact that the texture modification that it was to undergo would in fact be visually masked by the potato topping, which already matched the texture requirements. It was considered throughout the meals' development however that the detected differences in texture may not be extreme enough to incur a noticeable difference as only the meat mix component of the pie would have been altered. For that reason it was decided that the

potato topping for the two texturally different meals needed to be redesigned. For the texture modified meals, a usual mashed potato recipe developed to meet requirements of a “Texture C” diet was used. However for the standard texture meal, it was decided that the potato top would be sliced and layered to represent a potato gratin effect (Figure. 2.4). This was then topped with a thin layer of mashed potato (Figure. 2.4) to avoid visually altering the meal, and also to enable the enrichment of the potato topping for the energy dense standard texture meal. A standard method of texture modification was developed to be followed across all relevant meals (Table 2.5).

Table 2.5: Standard protocol for texture modification of the test meal

	Direction	Rationale
1	Once meat mix has cooked for designated time (Appendix 3) remove from heat and allow to cool slightly in saucepan before removing lid	Prevents moisture escaping as steam, potentially causing variety in texture amongst prepared meals.
2	When cooled slightly, blend mixture using handheld blender (ASDA, 250W) thoroughly until mixture represents smooth uniform consistency (Fig. 2.6))	Full description of desired consistency can be seen in Table 2.2.
3	If necessary, add extra chicken stock (with caution)	The quantity of liquid added is crucial to achieve the correct consistency. If there is not sufficient liquid the meal will not blend or sieve effectively, however if there is too much liquid the meal will not hold its own shape (Figure 2.6) and would in fact represent “Texture B” , “ <i>thin puree dysphagia diet</i> ” (BDA 2012a)
4	If adding more stock, add slowly (5 ml at a time)	From a clinical perspective, providing the incorrect texture to a patient with a swallowing disorder can result in an increased risk of fluid entering the lungs which may lead to chest infections, lung abscesses and aspiration pneumonia (SIGN 119 2010). From a technical point of a view, if the meat mix was too fluid, it would not be able to support the potato topping.
5	Stir with wooden spoon to check for lumps	Lumps present may pose a risk of choking for a dysphagic patient
6	If lumps persist after blending pass through sieve	To remove lumps which may cause choking in a dysphagic patient
7	Layer 670g meat mix in the serving dish	See portion size information (section 2.2)
8	Prepare potato topping as per recipe (standard energy or energy dense). Mash thoroughly ensuring no lumps present	Lumps may pose a risk of choking for a dysphagic patient
9	Layer mash potato on top of layer of meat mix using a spatula, adding small quantities at a time starting at the edges of the dish and working gradually towards the centre (Fig. 2.7))	To build a solid potato structure to avoid the potato sinking into the texture modified meat mixture, creating an uneven layer of potato topping.



Fig. 2.4: Standard texture test meal layers



Fig. 2.5: Blending meat component of test meal (ST→TM)

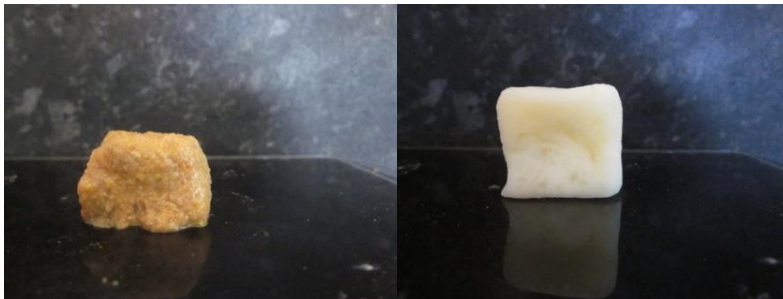


Fig. 2.6: Each meal component (left: meat mix, right potato top) demonstrating that it holds own shape as required (BDA, 2012b); Table 2.1).

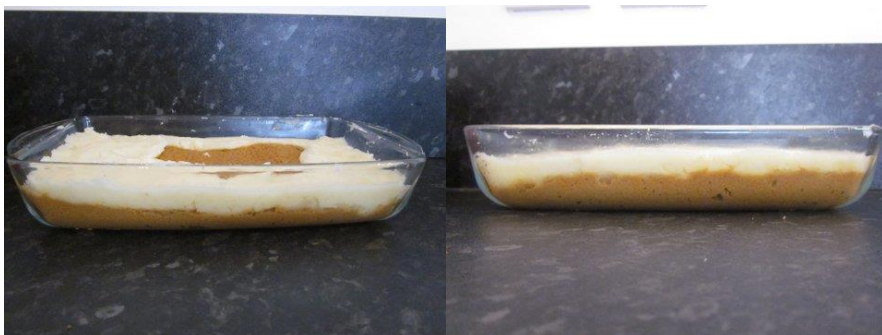


Fig. 2.7: Texture modified test meal (meat mix base topped with mashed potato)

2.2.2 Nutritional development

Table 2.6 outlines the nutrient breakdown of the test meals in both standard and enriched versions. All nutrients documented in Food in Hospitals (Scottish Government 2008) have been included, as well as the amount (%) the test meals contribute to the recommended provisions (meal, or daily basis (averaged over a week) as stated in the table).

It can be seen (Table 2.6) that the test meal was capable of being produced to both standard energy and energy dense guidelines (Scottish Government 2008) (Table 2.3). Data have also been presented which displays the percentage contribution that each of the test meals made on the overall recommended guidelines for provision of nutrients (*i.e.* the contribution that the SE meal made to the “nutritionally well” recommendations and the contribution the ED meal made to the “nutritionally vulnerable” contributions (Scottish Government 2008). This is in fact how food companies are required to present their nutritional information on food products (*i.e.* macronutrients and energy as a % of reference intakes (RI) (dictated by EU FIC (EU Regulation No. 1169/2011 on the provision of food information to consumers (EU FIC) this replaces the previous recommendation of % GDA). If presented, micronutrients are presented as a % of RDA (Food and packaging labelling legislation, (UK Government 2013))).

Table 2.6: Total nutrient composition of the test meals (per 390g portion) and their relative contribution to nutrient provision standards in place in Scottish Hospitals

	Nutritionally well guidelines (vulnerable guidelines)	SE meals (ST and TM)	ED meals (ST and TM)	% SE meal provides for “nutritionally well”	% ED meal provides for “nutritionally vulnerable”
Energy Density	N/A	1.0	1.4	N/A	N/A
Energy (kcal)	300 (500) (per meal)	385	537	128	107
Protein (g)	>18 g (per meal)	23.7	24.3	131	135
CHO (g)	≥50 % of energy	38.3	37.6	-	-
sugars (g)	≤10 of energy	8.9	8	-	-
Fibre (g)	18 g (daily)	4.2	4.1	23	23
Fat (g)	≤35 % of energy	16.4	33.4	-	-
Saturated (g)	≤11% of energy	5.1	11.6	-	-
Vitamin A (ug)	700 (daily*)	1620	1570	231	224
B12 (ug)	≥1.5 (daily*)	1.78	1.77	119	118
Folate (ug)	≥200 (daily*)	94	92	47	46
Vitamin C(mg)	≥40 (daily*)	22.9	22.6	57	57
Vitamin D (ug)	10 (daily*)	0.4	0.47	4	5
Calcium (mg)	≥700 (daily*)	86.0	68	12	9
Na (mg)	<2400 (daily*)	2118	2168	88	90
K (mg)	3500 (daily*)	1187	1162	34	33
Fe (mg)	8.7-14.8 (daily*)	3.5	3.5	24-40	24-40
Zn (mg)	≥9.5 (daily*)	4.4	4.5	47	47

* Averaged over 1 week

It should be highlighted however that this is an overly simplistic view of determining how requirements are met from one meal, since the recommended values that these are based on are intended to be met, on average over a period of a week. It does however provide useful insight into nutrients that may be lacking, or indeed present in large quantities in this meal, which could be used to inform the development of menus which over time (*i.e.* averaged over a week) ensure adequate provision of all nutrients. For example, it demonstrates that provision of Vitamin D in this meal is low (compared to recommended provision) therefore it would need to be considered that meals with higher concentrations of this vitamin would need to be offered within the menu to ensure that the recommended average intakes were met. It also highlights that despite the fact that only one meal is being considered here, that almost the full daily (averaged over a week) recommendation for sodium is met. Thus low sodium meals would need to be provided for the remaining meals on this day to ensure the target of < 2400 (daily*) was met.

Guidelines for the minimum provision of nutrients on a meal by meal basis were met (*i.e.* for energy and protein). This was achieved whilst also maintaining the protein and fibre contents across the meals, which due to their potential impact on appetite (section 2.1.2) was a key consideration during the test meal development. It was specifically considered that in some cases, during the production of a TMD meal that the fibre content may be altered (increased or reduced). It may be reduced due to sieving to remove fibrous material (Table 2.2) ensuring a meal of a uniform texture. Whereas in the case of thickened fluids in particular, fibre based thickeners may be added to facilitate safe consumption, by allowing greater control during the transit from the oral phase to the oesophagus (chapter 1, section 1.4.2).

In the current study, the meal was developed to meet the guidelines for “Texture C” meal (BDA 2012a) without the addition of any commercial thickeners. Also, the meal did not require sieving as the ingredients were chosen to specifically allow modification through blending alone. For example, it was for this reason that onions were excluded from the recipe and replaced with an onion powder (Table 2.4). Including onion would have resulted in a discrepancy in fibre content between the standard texture and texture modified meals as the texture modified meals would have to have been sieved to remove the fibrous component of the onion.

The “energy dense” meal needed to be enriched as per the guidelines (Food in Hospitals, (Scottish Government 2008). By enriching the potato component of the meal, both the meat base and potato top were similar in energy content (Table 2.7). Considering findings by Wilson et al. (2000) which demonstrated that on average, patients consumed 67 % (Mean (SEM): 165 g (14g) consumed from 246 g (14g) served) of their main meal (plated system); therefore in this current study, by serving both meal components with similar energy content, would have a less substantial effect on total energy intake if for example one component of the meal was consumed in a greater quantity than the other. Also in the clinical setting mashed potato would be commonly enriched, mainly using store cupboard items such as cream, cheese and butter (The Christie NHS Foundation Trust 2012; Norfolk and Norwich University Hospital NHS Foundation Trust 2013; Stockport NHS Foundation Trust 2013).

From a practical point of view, these items are often more affordable, available and may be a more realistic method of enriching food long term, in domestic and residential settings. Previous studies have also demonstrated their success for the

purpose of energy enrichment and resulting increased energy intakes at meals (Gall et al. 1998; Odlund Olin et al. 1996; 2003). The appearance and palatability of foods determine the magnitude of voluntary nutritional intake (Blundell and Stubbs, 1999). Typically, texture modified diets can be less appealing than their unmodified counterparts and this factor may further impact on their consumption. Achieving and maintaining palatability is therefore crucial to ensure these therapeutic meals are actually consumed. Using high fat ingredients such as butter, cream and cheese may improve the aesthetics of the meal as fat is known to be highly palatable (Blundell and MacDiarmid 1997; French and Cecil 2001). It is therefore argued that enriching a texture modified meal with these palatable fat based ingredients, will not just increase the energy density, but also the palatability potentially promoting increased intakes.

Table 2.7: Individual pie components energy and protein content *

	Energy (kcal)	Protein (g)
Standard Energy (390g)		
Whole pie	385	23.7
Meat mix	229	19.6
Potato top	156	4.1
Energy Dense (390g)		
Whole pie	537	24.3
Meat mix	282	20.5
Potato top	255	3.8

* Per 390 g cooked weight portion

In the current study the higher energy density was therefore achieved by the addition of double cream, and fat spread. Fat (60%) spread and semi skimmed milk were used to prepare the standard energy meal in order to improve the flavour and texture of the potato topping. For the energy dense potato topping, a fat spread with a higher fat

content was used (75% fat versus 60% fat). The potato topping of the energy dense meal contributed 255 kcal versus 156 kcal for the standard energy version. The protein content of the energy dense potato top was matched between the meals (both potato tops contained ~4 g protein). The meat mix (of the ED meal) had a slightly higher meat content (85 g versus 80 g) which contributed an extra 0.9g of protein (per 390 g portion). This extra protein present in the meat mix was partially balanced by the slightly lower protein content (0.3 g) of the energy dense potato topping yield a net difference of 0.6 g between the standard and energy dense meal protein contents. Overall this is a very small difference in total protein content and was therefore unlikely to cause a difference in intakes.

Table 2.8 displays an overview of the macronutrient content of the test meals and how these values compare to similar meals available for use in hospitals. These values differ as each manufacturer is using different (inaccessible) recipes. Also, each manufacturer advocates different portion sizes. The portion sizes have therefore been standardised across the meals (390g) to facilitate comparisons in macronutrient content between meals. It has also been considered if the “meals” served contained additional foods served alongside the cottage pies. For example for the “cottage pie meal” served by Wiltshire Farm Foods (WFF), the cottage pie is served with a portion of peas. The amount of peas served has therefore been estimated (using the ingredient information stating that peas made up 13% of the product) and then estimating the nutritional content using information from WinDiets (WinDiets 2005). The nutritional content from the peas has then been deducted from the total meal nutritional information as circled (red) in Table 2.8

Table 2.8 Nutrient composition of the test meals compared to alternatives

Meal	Portion (g)	Energy (kcal)	Protein (g)	CHO (g) (Sugars (g))	Fat (g) (Saturated (g))	Fibre (g)
Standard energy test meals	390	385	23.7	38.3 (8.9)	16.4 (5.1)	4.2
Energy dense test meals	390	537	24.3	37.6 (8)	33.4 (11.6)	4.1
WFF cottage pie (as served*)	430	564	23.3	50.3 (14.6)	29.2 (5.1)	6.4
WFF cottage pie (comparable serving, no peas)	390	468	17.2	40 (12.5)	25.5 (4.4)	3.3
HCA Cottage pie (as served)	266	286	20	18 (6)	15 (5.8)	2.8
HCA cottage pie comparable serving	390	419	29.3	26.4 (8.8)	22 (8.5)	4.1
Nutrifresh Cottage pie (as served)	160	196	12.3	12.4 (2.9)	10.3 (9.0)	N/A
Nutrifresh cottage pie (comparable serving)	390	478	30	30.2 (7.1)	25.1 (21.9)	N/A

WFF: Wiltshire Farm Foods, HCA: Hospital Caterers Association

*Peas (boiled in unsalted water) nutritional information per serve (56g): 44 kcal, 0.9 g fat, 0.2 g saturated fat, 3.8 g protein, 5.6 g CHO, 0.7 g sugars, 2.5 g NSP.

Nutritional analysis of the test meal was conducted using the nutritional analysis programme WinDiets (WinDiets 2005: Robert Gordon University, Aberdeen, UK). Where data for specific ingredients were missing from the database, the researcher sourced the relevant nutritional content from the packaging and added the information to the database as a “local food” allowing accurate analysis of the test meal recipes.

Further, to ensure greater accuracy of nutritional calculation, the researcher quantified the expected weight loss that was experienced with cooking the main non liquid ingredients used in the meat mix in order to understand where the losses were coming from. The tomato puree was concentrated therefore expected moisture loss was negligible, and also the onion powder did not contain any moisture to lose during cooking therefore these ingredients were not included while estimating moisture losses. This estimation was done by weighing out the ingredients as per an individual portion, followed by cooking the ingredients separately, and then weighing the final yields individually. The percentage weight loss (Table 2.9) was then calculated using the formula (Food Standards Agency 2002; McCance and Widdowson) as follows.

Formula for estimating weight changes with cooking (Food Standards Agency: McCance and Widdowson, 2002)

$$\frac{(\text{Weight cooked} - \text{weight raw})}{(\text{weight raw})} \times 100 = \% \text{ change}$$

Table 2.9 Estimated losses experienced with cooking

	Raw weight(g)	Cooked weight (g)	% Change
Meat	80	68	-15%
Carrots	80	68	-15%
Mushrooms	20	16	-20%

Using the estimations (Table 2.9), the expected yield was calculated for the ad libitum test meal (Table 2.10). The pot was covered as soon as the chicken stock and Worcester sauce were added (+ 209.5 g) to prevent further losses. A final yield of

meat mix of 670g was expected (which allowed 9.0g (~1% of total meat base) of extra weight loss should any further accidental moisture losses occur. Root vegetables do not typically change their weight with cooking therefore the same calculations were not performed for the topping of the pie.

Table 2.10: Expected moisture losses experienced with cooking.

Ingredient	% loss	Cooked weight (g)
Meat	15% of 240g = 36g	204
Carrots	15% of 210g = 31.5g	178.5
Mushrooms	20% of 90g = 18g	<u>72</u>
		= 454.5
		<u>+ 15.0</u> (onion powder and tomato puree)
Total cooked weight: (meat base without stock and Worcester sauce added)		469.5 g *

*Chicken stock plus Worcester sauce (weighing an additional 209.5 g) added later

The nutritional composition was calculated using information (weights and nutritional contents) of the raw ingredients as these were known weights across meals. As it was not feasible to measure moisture losses across each of the meal components for all meals, the level of variation in change in weight with cooking was unknown. It was therefore considered that by using the information for the raw components, a more accurate measurement of what was included in each recipe could be obtained.

Any change in weight as a result of cooking was likely attributed to moisture loss which is likely to be more important for changes in micronutrient content (*i.e.* water

soluble vitamins), which was not a focus of this current study. Changes in micronutrient content of meals provided to patients do need to be considered within menu planning, to ensure that all nutrient requirements are being met long term. Also the meal wasn't drained after cooking therefore any fat that may have been lost from the meat remained in the meal. As moisture changes occurred with cooking, the % contribution of each macronutrient to total energy would also have changed based on the raw weight. For this reason these values were recalculated as a percentage of the cooked weight.

2.2.3 Cost estimation of test meal production

As discussed in chapter 1 (section 1.3), ensuring hospital food provision is cost effective is imperative. In 2004/05 the NHS spent £73 million on catering services in Scottish hospitals (1% of total budget). There is a tight catering budget in place with most recent available reports estimating the amount spent on food and beverages (excluding operating costs) to be £2.34 per person per day (Audit Scotland 2006). Whilst the data are not relatively recent, with recent budget cuts outlined in the white paper, *'Equality and Excellence – Liberating the NHS'* (Department of Health, 2010b) outlining that the NHS is required to cut £20bn from its annual budget by 2015, it is unlikely that this expenditure has increased.

Table 2.11 displays the estimated cost to produce each portion of each of the test meals, as costed by purchasing the ingredients from local retailers. The test meal for this research was produced on a much smaller scale than what would likely be the case in the hospital setting. Thus the estimated costing below (Table 2.11) will not be

directly comparable to how much it would cost to produce in a hospital setting. It is likely that the cost of ingredients would be cheaper in the hospital setting as orders can be made in bulk, which often reduces cost per unit. Further, contracts and tenders in place at a national level may result in cost negotiations and customer loyalty incentives also reducing costs. It should be identified that, costs outside those incurred from purchasing the raw ingredients are not considered here, nor were they reported within the estimation of daily expenditure on food ingredients by Audit Scotland (2006) above (*i.e.* £2.34 per person per day).

Table 2.11: Overview of the estimated cost of ingredients for each test meal:

Domestic setting:	ST SE	ST ED	TM SE	TM ED
Total cost of test meal as served (1170g)	£ 2.92	£ 3.13	£ 3.56	£ 3.78
Total cost of test meal per standard portion (390g)	£ 0.97	£ 1.04	£ 1.19	£ 1.26

Table 2.12 gives further context to the cost of the test meal in comparison to similar meals that may be offered in the hospital settings, and how these relate to the amount spent on food ingredient expenditure. These demonstrate that the production of TMD meals on-site is potentially much more affordable than outsourcing to external producers. Whilst the cost of additional labour is not accounted for, it is likely that it falls below £2.98 per meal (*i.e.* cost difference between the TM SE test meal and the puree cottage pie produced by Wiltshire Farm Foods). This assumption has been

based on the fact that the additional processes in producing a TMD meal takes no more than 5 minutes per meal, which translated to labour costs would be £0.53 (based on minimum wage as £6.31 per hour).

Table 2.12 Cost of producing test meals as % of daily food expenditure per person compared with “ready meal” versions

	ST SE	ST ED	TM SE	TM ED
Total cost of test meal* as prepared in the domestic setting	£ 0.97	£ 1.04	£ 1.19	£ 1.26
Energy (kcal) content 390g	385	537	385	537
Cost as a % of estimated average daily expenditure (DE) on food (approx. £2.34 Audit Scotland, 2006)	41%	44%	51%	54%
Cost of comparable “ready meal” (adjusted for serving size) (Wiltshire Farm Foods)	Extra tender cottage pie		Puree cottage pie	
	Cost (% of DE)	Nutrition	Cost (% of DE)	Nutrition
	£3.25 (140%)	454 kcal	£4.17 (178%)	494 kcal
Difference compared with test meal	vs. ST SE	vs. ST ED	vs. TM SE	vs. TM ED
	+ £2.28 + 99 kcal	+ £2.21 - 83 kcal	+ £2.98 +109 kcal	+ £2.91 -43 kcal

* per standard portion (390g)

2.3 Development of research protocol: Feasibility study

The research protocol that was to be used in the main study was informed by experimental appetite studies and using standard methodology in the field (section 2.1). The feasibility of running the experiment needed to be trialled before a final research protocol could be decided. Therefore, prior to commencing the main study, a feasibility study to assess the proposed research protocol, was carried out (April, 2011). By their nature, feasibility studies are used to estimate important parameters

needed to design the main study, however do not always seek to measure the outcome of the study (NIHR 2013). Feasibility studies are also undertaken to assess the practicality of proposed methodology. An overview of the steps involved in running the testing sessions and issues/ steps to be clarified are identified in Table 2.13.

As the proposed research protocol was informed using experimental studies and standard research methods used to assess food manipulations on appetite, it was unlikely that these would need to be adapted for the main study. The aim of this feasibility study was therefore to identify any issues with the proposed protocol which could then be addressed prior to commencing the main study. If these issues were not identified until during the main study, leading to changes in protocol; earlier data may be confounded and therefore could not be included in the final analyses.

Objectives

- To ensure that the researcher could feasibly run the session with four participants at a time, within the allocated time period.
- To ensure that the workbook and instructions were comprehensive and effective for assessing appetite parameters over the session.
- To assess the quantity of food to be served in order to allow ad libitum feeding.
- To gather feedback from participants regarding the protocol, in terms of structure and potential compliance issues.
- To inform the set up and management of the databases to be used in the main study.

Table 2.13: Overview of uncertainties of proposed research protocol

Stage of protocol	Query	Action
Explanation of research protocol	Unclear if the researcher could adequately explain what was required of the subjects without disclosing the outcomes being measured, and the alterations to be made	Observe that protocol was followed correctly and seek feedback from subjects (evaluation sheets).
Test meal: serving	Unclear if the subject should have ad libitum serving of test meal out of sight to avoid additional impact on intakes	Observe flow and seek feedback from subjects (evaluation sheet)
Test meal: serving	Unclear what quantity of test meal should be prepared to allow ad libitum feeding	Assess amounts needed to be consumed until satiation was reached
Test meal: development and serving	Unclear if the test meal acceptable in terms of palatability	Assess palatability ratings of test meal at start and end of session
Overall logistics of running testing sessions	Unclear if the researcher will be effectively able to run the testing sessions whilst managing participants and collecting data.	Feasibility study allows researcher to familiarise herself with the procedures and identify any potential issues with running the sessions effectively
Appetite assessment using workbook containing instructions and nine VAS to assess appetite over the testing session period	Unclear if the workbook containing instructions to participants and VAS is comprehensive.	Assess participants view of the ease of completion of workbook using an evaluation sheet at the end of the session
Number of subjects per session	Unclear if researcher could manage four subjects at a time whilst ensuring they could not interact with each other or observe each other's intakes	Reduce maximum permitted numbers per test session if four subjects proves to be too many at one time
Data collection	Unclear if asking too much of participants within session (<i>i.e.</i> VAS and time recording of satiation)	Observe flow of sessions and seek feedback from subjects
Data collection	Unclear how accurately researcher would be able to measure plate wastage.	Trial plate wastage method and identify where any errors may occur
Data management	Unclear of the best way to set up data management databases.	Generated data from feasibility study can inform the construction of databases

2.3.1 Feasibility study procedure

To mimic the maximum number of participants that resources could allow to attend each testing session, four participants were recruited for the feasibility study using an information flyer (Appendix 4) via moderator email within QMU. As it was hoped that the main study would successfully recruit adults >50 years, all subjects for the feasibility study were greater than 50 years in order to have a representative sample. Participants were excluded if they were receiving a therapeutic diet of any kind, had any metabolic disorders where fasting may cause complications, or if they had allergies to any of the test ingredients. Once individuals expressed interest in the study, they were contacted by the researcher to arrange a consultation session and identify dates that they would potentially be available to attend a testing session should they agree to participate.

The consultation session allowed the researcher to meet the potential subjects and explain the aim and protocol of the study in more detail by going through the information sheet. Individuals also had the opportunity to ask any questions relating to the study at this stage. The researcher then showed individuals the workbook that was to be filled out during the testing session and explained what was required in order to fulfil its completion. If individuals were happy to participate, they were asked to provide written informed consent and were then considered “participants”. The time and date of the testing session was then arranged and it was also explained to participants that they would need to consume their regular breakfast and then fast for at least four hours prior to the session in order to gauge the quantity of food that would be required for them to reach satiation from a fasted state. The whole consultation process took no longer than 15 minutes.

On the day prior to the testing session the researcher prepared the test meal (Appendix 3a) in four separate roasting dishes (26 cm) with each dish containing three standard portions in order to allow ad libitum feeding. The test meal served in the feasibility study was a beef based cottage pie (standard texture, standard energy density) and was one of the four test meals that were developed for use in the larger study. The pies were stored in a refrigerator overnight (4⁰C) and then the final stage of cooking took place 40 minutes prior to the testing session. Tables were arranged in rows in order to avoid communication between participants which may have affected appetite ratings and food intake. Each participant had their own two person desk with the study material set up identically. On each desk, there was a glass (200ml volume) which was filled with still bottled water, a white plate (18cm), a set of cutlery (knife and fork) enclosed in a plain napkin, a pen, a copy of the workbook containing the visual analogue scales, and a sheet reiterating the outline of the session and the evaluation sheet.

Participants entered the laboratory in a fasted state (*i.e.* fasted since consuming breakfast at 8.30am) at 12.25pm to ensure prompt initiation of the testing session at 12.30pm. Once participants had settled in their designated seats they were asked to record their baseline appetite responses using a visual analogue scale (VAS). A detailed description of the VAS scales used in this study can be read in chapter 3, sections 3.4.2 and 3.5.4). The researcher then presented each of the participants with an individual dish of cottage pie (1170g). This was placed to the side of each participant such that they were required to stand in order to serve themselves. It was thought that having the test meal out of direct sight would allow a more accurate measurement of intake related to feelings of hunger, rather than due to the impact

that seeing the test meal may have on intakes. Participants were required to consume the meal until they reached satiation, while rating their feelings of appetite at designated time points prompted by the researcher.

Participants recorded the time that they reached satiation. They then alerted the researcher after which their plate and cutlery were taken away. Participants were required to stay until the end of the one hour session and to answer all the questions in the workbook regardless of their state of satiation. In total, their appetite responses were measured nine times over a one hour period. When the testing session was over, participants completed their evaluation sheet (Appendix 5) which asked them to provide feedback about the session, and the workbook instructions.

When the participants had left the laboratory the remains of the test meal were weighed in order to quantify the amount (g) of the test meal consumed to the point where the participant indicated satiation. This was done by weighing the plate and remains on the plate, and also the dish and remains in the dish. Weights of the plate and dish were then subtracted in order to attain the weight of left over meal. The researcher also separated the meat mix (beef, carrots, mushroom, etc.) and potato topping in order to be able to calculate the exact energy intake (kcal) consumed as these components differed in energy density and protein content.

Corresponding databases were created to store and manage the data. The first database (Microsoft Excel 2010) was designed to collate the information regarding the weights of the test meal and apparatus. It was set up using appropriate formulae to calculate the quantity of test meal consumed as well as energy (kcal) and protein (g) intake taken from the calculated energy and nutrient composition of the standard

recipe. The amount of each nutrient consumed as a percentage of what was provided could also be determined. The second database; (SPSS for Windows (version 17.0, 2009, SPSS Inc. Chicago, IL) was designed to store all the participant data, including demographic information and energy intakes (at breakfast, the test session, post-test session, and the overall 24 hour intake), and appetite responses (mm) for all test meals.

2.3.2 Feasibility study outcomes and implications for main study:

The feasibility study was extremely useful as it gave the researcher a clearer idea of the flow of the testing session and identified potential issues within the experimental protocol prior to commencing the main study. Table 2.14 displays the information obtained from conducting the feasibility study and the implications for the main study. A full description of the final research protocol developed using standard appetite assessment methodology as well as what has been learnt from experimental and clinical studies and from this feasibility study, can be read in chapter 3.

Table 2.14: Observations from feasibility study and implications for main study

Observation from feasibility study	Implication for main study
Consultations prior to testing sessions were sufficient to explain research protocol research workbook	Consults including full explanation of research protocol were conducted in the main study. These were however expanded to include height and weight measurements and assess dietary restraint (using validated questionnaire described in chapter 3)
Final serving size of 1170g (500g potato , 670g meat mix) was adequate to allow ad libitum feeding	Test meals were prepared in 26 cm roasting dishes which held 3 standard portions of the test meal thus allowing ad libitum feeding to reach satiation.
Subjects felt everyone noticed them serving themselves more of the test meal, impacting on behaviour. A participant feedback that he liked the small size of the plate used in the study, and meant he did not feel discouraged to refill the plate during the session.	The test meal was set up such that it was within reach of the subjects. It was good that the test meal was not immediately in sight as this may encourage/discourage intakes regardless of motivation to eat. Therefore the subjects were asked to keep the serving dish covered during the session. The small plate was used in the main study, which helped to get an accurate measure of the real quantity of the meal (g) necessary to reach satiation.
Meal was rated to be palatable (>50 mm on VAS) and remained > 50mm for the session. The temperature remained acceptable throughout the session.	Test meal was rated to be acceptable (as served in its “standard “state, <i>i.e.</i> ST SE). The meal was therefore to be brought forward for use in the main study without further development.
Participants fed back that the session ran for the appropriate length of time.	Session timings did not change for the main study. The researcher was based at the back of the lab, to ensure the subjects did not feel like they were being observed which may alter their behaviour.
Appetite assessment using workbook containing instructions and VAS was universally comprehensive	This was used as it is in the main study. As a precaution, an overview of the testing session procedure (Appendix 9) was placed on each desk which subjects could refer to if they needed to.
The researcher could successfully manage four participants at a time	No more than four subjects were permitted at each testing session. A session with four people allowed the lab to be set up such that the subjects could not interact.
Researcher unsure if participants accurately recorded the time they reached satiation	In the main study the researcher recorded the time that each participant reached satiation to ensure accuracy and also reduce burden on the subjects.
Plate wastage measurements, including separation of meal components were feasible.	The test meal components were separated for weighing to more accurately estimate energy intakes.
Data management: The feasibility study fully informed the set-up of the database for data managements.	For the main study, this was expanded to take account of all four meal occasions, as well as additional demographic information that was collected in the main study.
Water intakes may differ between subjects, affecting appetite	Water intakes (ml) were recorded in main study.

Chapter 3:

Research methodology

3.1 Study pre-requisites

Prior to commencing the study the researcher obtained ethical approval, food hygiene training and certification (REHIS) and Enhanced Disclosure for working with older adults. Ethical approval for this research (main study and feasibility study) was granted by the Human Research Ethics Committee of Queen Margaret University, Edinburgh (April, 2011). Any amendments made to the ethics application during the study are documented throughout.

3.2 Study design

This experimental study was a single-blind, randomised, crossover, repeated measures study design, where each participant acted as their own control, thereby minimising the impact of confounding covariates. The overview of how the concept of the study arose, and the literature studied in order to design the study can be read in chapter 2.

The research comprised of four one-day testing periods which aimed to measure the impact of texture modification (food form) and energy enrichment (energy density) on appetite, satiation and satiety in healthy adults. Both independent variables; texture, and energy density each had two levels, resulting in a total of four test meals. On each individual test day, participants were presented with one of four test meals

with either altered texture and/or energy density. Meal code serving order was randomised to eliminate the potential of biased results based on the introduction of an “order effect”. Following simple randomisation the researcher randomly drew the four meal codes to yield meal sequences which were then assigned to the testing dates. Subjects received the test meals in a randomised order based on the dates of the sessions they were able to attend, ensuring each subject received each test meal. Subjects were unaware of their randomised meal sequence prior to the sessions.

3.3 Subjects:

3.3.1 Study sample

Healthy men and women aged ≥ 18 years with a BMI up to 30 kg/m^2 who expressed general liking for the test meals were considered for the study (i.e. inclusion criteria). Individuals were excluded if they were allergic or intolerant to any of the test foods, were suffering from any medical condition or were taking medication that may affect appetite, were incapable of feeding themselves, had any metabolic disorders, wore dentures, were receiving special/therapeutic diets, were unable to give informed consent, or were exercising dietary restraint (as shown by the Three Factor Eating Questionnaire (TFEQ), discussed in section 3.4.1) (Stunkard and Messick 1985) responses.

3.3.2 Power calculation

In arriving at an estimation of sample size, two approaches were adopted; i) the overall Repeated Measures ANOVA and, ii) the post hoc paired t-tests. The implied single-group RM ANOVA, for a sample size of 30, with a 0.05 significance level would have 80% power to detect a difference in means across the levels of the repeated measures factors characterized by an effect size of 0.1. Following any significance here, post hoc tests (paired t-tests) for the four planned analyses (*i.e.* between each pair of conditions namely, texture and energy density combinations), were undertaken to identify where significance lies. The sample size calculation had been determined for unadjusted post hoc paired t-tests. A sample size of 30 would have 80% power to detect an effect size of 0.5 using a paired t-test with a 0.05 two-sided significance level (nQuery Advisor 7.0). It was intended to recruit a sample size of 35, allowing for attrition of approximately 15%.

The effect sizes observed from similar studies have been calculated (Table 3.1), where

$$\text{Effect size} = [\text{experimental group mean values}] - [\text{control group mean values}]$$

Pooled standard deviation (SD)

(Coe 2002)

$$\text{Pooled standard deviation} = \frac{\sqrt{SD_1^2 + SD_2^2}}{2}$$

(Cohen 1988)

In studies where the standard error (SE) was reported, the SD was calculated using following formula; $SD = SE\sqrt{n}$ (Thalheimer and Cook 2002).

Table 3.1: Power and sample size calculations of similar studies

Study	Study design and variations in energy density	Mean (SD) energy intakes of experimental group	Mean (SD) energy intakes of control group	kcal diff	Effect size
Odlund Olin et al. 1996 (daily EI) n=36	Crossover design Regular: 1670 kcal/day Enriched: 2520 kcal/day (each for 6 weeks, equal volumes)	1825 (276)	1347 (174)	478	2.1
		Pooled SD: 231			
Latner et al. 2008 n=30 (group 1: n=15, group 2: n=15)	Repeated measures design Regular: 1.0 kcal/g Enriched: 1.6 kcal/g	524 (100) (SD not reported-estimated from graph)	349 (80) (SD not reported-estimated from graph)	175	1.9
		Pooled SD: 90.5			
Silver et al. 2008 n=45	Randomised Crossover design. Regular diet: 1.1 kcal/g Enriched diet: 2.2 kcal/g (+10 g protein per serving)	Lunch: 774 (220)	415 (104)	359	1.9
		Pooled SD: 187			
		Daily: 1876 (525)	1423 (417)	453	1.0
		Pooled SD: 474			

The determined effect sizes from these similar studies (Table 3.1) were very large suggesting that, it was likely that there would be a large effect (*i.e.* large difference in resulting energy intakes) observed with the intervention (*i.e.* enrichment). Based on the determination of sample size for the current study (nQuery Advisor 7.0) 30 participants would be powered (80%) to detect even small differences (0.1). Based on the literature surrounding energy density manipulations of food on intakes (chapter 1, section 1.6.2) it was apparent that individuals tend to consume similar

quantities of foods regardless of the energy density. Thus as the test meals in the current study differed by 152 kcal per standard portion (chapter 2, section 2.2.2), it was likely that the difference in consumed energy intake between the enriched and standard meals would reflect this. Blatt et al. (2011) assumed that a minimum difference in daily energy intake of 200 kcal was necessary to be clinically different. Therefore, this design was likely to contribute to a significant clinical difference also, once subsequent energy compensation did not occur.

3.3.3 Recruitment strategy:

Individuals were recruited to this study between May 2011 and June 2012 via convenience sampling methods. The two main goals of recruitment were; to recruit a sample that adequately represents the population and, to recruit sufficient participants to meet the sample size and power of the study (Patel et al. 2003).

As the research findings were most likely to have application in an older population, it was intended to recruit an adult population aged ≥ 50 years. This age group is representative of a group who may be at greater risk from suffering from stroke (Sacco et al. 1997), and neurodegenerative conditions associated with advancing age which may lead to the development of dysphagia (Rofes et al. 2011), and the prescription of a TMD. No upper age limit was imposed once all other participation criteria were met (section 3.3.1).

Older adults are however typically a difficult group to recruit; with greater age being attributed to adversely affecting response rates (Patel et al. 2003). Therefore, to

ensure sufficient participants were recruited to meet the required sample size, and considering the barriers to recruitment (discussed subsequently within this section) it was possible that the age restrictions in place may need to be re-evaluated. It was decided to assess this after a period of 8 months (in December 2011) of initial recruitment.

First stage recruitment:

A number of local groups of potentially healthy older adults were identified, namely; members of the Centre of Older Persons Agenda (COPA), members of the University of the Third Age (U3A), QMU staff, mature students and alumni, local community groups for the over 50's (Keeping in Touch Edinburgh (KiTE), ACE it, and Age Well), local community run lunch clubs, and the meeting of the Scottish Older People's Assembly (in conjunction with A City for All Ages, Edinburgh).

All recruitment materials used (posters, flyers, information sheets and consent forms) to attract the interest of potential participants were approved by the Human Research Ethics Committee of Queen Margaret University, Edinburgh (April, 2011). Individuals aged ≥ 50 years were recruited using an informative flyer which was distributed via COPA. This group offered to distribute to those individuals (confidential list) aged 50 years or more who had registered interest about taking part in research carried out in adults and older adults. Individuals were provided with contact details (address, email, and telephone with 24hr voicemail access) of the researcher if they wished to find out more information about the research or register their interest in potential participation. This same flyer was also circulated throughout the university (QMU) via the research recruitment moderator system (to

attract interest from staff members), throughout members of University of the Third Age (U3A), and throughout local community groups that were run specifically for the over 50's (KiTE, ACE it, Age Well). To reach the general public who may not be involved in community groups, flyers were displayed in supermarkets, local shops, cafes, libraries, and community centres.

The researcher also registered to attend the annual meeting for members of the Scottish Older People's Assembly (SOPA) (25th October 2011, EICC Edinburgh). This steering group (supported by Edinburgh Council- a City for Ages) allowed access to a number of delegates (approximately 150 attendees) aged >50 years with an active interest in promoting the health and quality of life of older adults. During the meeting, delegates were approached and informed about the current research project to raise awareness and potentially recruit members to take part. Each delegate also received an information pack from the meeting, which included the flyer advertising and reinforcing the research, whilst providing contact details of the researcher.

A second flyer (Appendix 7b), tailored to attract the interest of carers in the local community was also created. It was thought that this group of individuals may be particularly interested in participating in research of this nature due to the possibility of encountering the difficulty of the people for whom the care, meeting their adequate food and energy intake. This flyer was distributed via a contact at the organisation, "Care for Carers" based in Restalrig in Edinburgh. The flyer was delivered alongside the newsletter (bi-monthly) which targeted 700 individuals from the local area (Restalrig, Craightinny and Lochend). A franked addressed envelope

and a reply slip was included with the posted flyer allowing individuals to provide their contact details should they wish to receive more information/be contacted about the research. Contact details for the researcher (address, telephone (with 24hr voicemail access) and email address were provided.

Due to budget constraints there were no incentives to participate other than the knowledge that participation may benefit others in the future. The majority of the research budget was allocated to the cost of producing the test meals, as well as the production of research materials. Participants were informed at the first point of contact with the researcher that no financial compensation would be provided for taking part. Reasonable transport costs (*i.e.* rail and bus fares) however would be reimbursed once receipts were provided.

When the researcher received notice of expressed interest, the potential participants were contacted to explain the research in further detail, including the requirements of the study and the inclusion criteria. Participants who remained interested in participating and who were thought to meet the inclusion criteria were then invited to QMU to attend a consultation session (section 3.4.1).

Barriers to recruitment:

Barriers for successfully recruiting sufficient participants have been identified based on findings from other studies, and feedback from potential participants. It is already documented that recruitment response rates drop with greater age (Armstrong et al. 1992). In fact, subject recruitment failure is reported to be typically 50% in older adults (Ridda et al. 2010). Older adults may be harder to recruit due to frailty which

may make participation too demanding, as well as cognitive decline leading to problems with consent and retention (Carroll and Zajick, 2011)

Added to the usual barriers of recruiting an older sample, are the specific inclusion/exclusion criteria applied to this research. It was essential that participants for this study were healthy, had no metabolic disorders, and not using medications that may affect appetite. Poor health status or the needs for medical treatment are known to adversely impact on response rates (Patel et al. 2003) however in this case those individuals are excluded from the outset. Those wearing dentures were also not permitted as they may need to restrict certain foods.

The number of individuals aged ≥ 50 years with one (or more) of these criteria is likely to be high, as the risk of these can increase with advancing age. For example increased risk of disease occurs with advancing age, as well as the need for dentures due to decreased oral health status associated with advancing age (Lamy et al. 1999). This therefore limits recruitment from an older sample to this particular study.

Furthermore by excluding those who are obese, a large section of the adult population are essentially excluded from the project. It is reported that 27% of Scottish people aged 16-67 are obese (BMI 30 kg/m^2) (Scottish Health Survey, 2010). Further results from the National Diet and Nutrition Survey (headline results from 2008-2010) (Bates et al. 2010) report that 27% of adults aged 19-64 are obese or morbidly obese, whilst 31 % of adults aged >65 years are obese.

The number of people following weight loss, special or therapeutic diets is unknown, however 2 % of the adult population (19-64 years) and 1 % of the older adult

population (65 years +) report to be vegetarian (Bates et al. 2010), automatically excluding them from this study.

To specifically assess reasons for poor interest in participation the researcher visited a lunch club (The Ripple Project, Restalrig Edinburgh) where the project had been advertised. Of the seven members present at the lunch club, none were suitable for the study due to not meeting the inclusion criteria (Table 3.2). Coupled to this was the fact that a number of the members expressed concern about travelling to the laboratory as typically they rely on community shuttles or family members, and would need to be accompanied to the sessions which is not always possible.

Table 3.2: Qualitative feedback: reasons for poor response rate

Lunch club member	Interested in study	Reason for not enrolling in study
Male, 96 years	No	Frail, dentures, medications, unable to travel
Male, 91 years	Yes	Partial edentulism (requires special foods), medications
Male, 69 years	Yes	Obese, medications
Female, 67 years	Yes	Obese, medication, diabetic
Female, 90 years	Yes	Vegetarian, unable to travel
Female, 74 years	No	Diabetic, post stroke, unable to travel
Female, 87 years	Unsure	Frail, cognitive decline and confusion.

Second stage recruitment:

As planned, the recruitment strategy was re-evaluated in December 2011. At this stage, 12 adults aged ≥ 50 years had enrolled in the study. It was therefore decided to

open recruitment to those aged ≥ 18 years in order to increase recruitment numbers. Although this age group may be arguably less representative of the group that the study findings are likely to apply due to the fact that the need for consumption of a TMD is not limited to older adults, coupled by the general lack of food based studies investigating strategies to manage malnutrition suggests that it would be justified to conduct this study in a sample of varying ages. After all, this research was being conducted in a healthy population therefore the impact of disease state and dysphagia on intakes was not actually being specifically investigated in this study. A within-subject study design will also control for any inter-individual variations occurring as a result of including various ages. Further, reducing the mean age group of the sample by including younger subjects potentially increased the sensitivity for detection of energy compensation at subsequent intakes as a result of the test meal alterations. This was because the ability to accurately compensate energy intakes is reduced with advancing age (Rolls et al. 1995a; Appleton et al. 2011).

After deciding to reduce the age inclusion criteria, a new flyer was developed (Appendix 7a) reflecting this change, and an amendment to ethical approval was sought (granted, December 2011). Individuals aged ≥ 18 years were then recruited via the research recruitment moderator system in place in the university which is sent in email format daily reaching approximately 5000 students and staff (QMU 2013). Flyers that were previously displayed in the local community were replaced with the new flyer including the amended age inclusion.

The flyers recruiting those ≥ 50 years that were displayed in specific areas were left as it was hoped to continue to recruit those over 50 years to ensure a balanced sample since the university population is typically characterised by younger adults.

Figure 3.1 demonstrates the flow of individuals from advertising for recruitment to screening to enrolment. As a crossover design was being followed, each individual participated in each meal following simple randomisation.

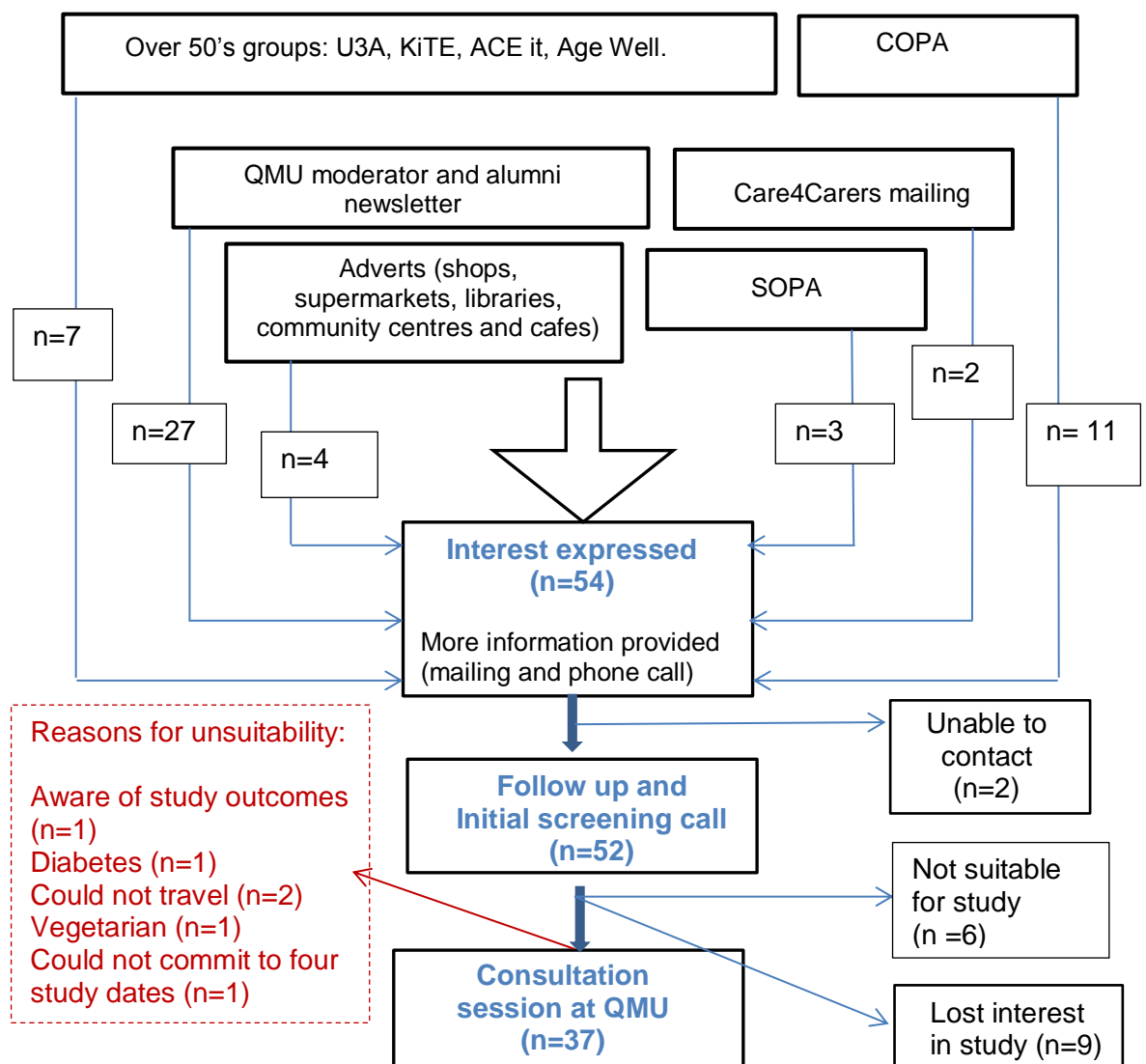


Figure 3.1: Overview of the recruitment of participants.

3.4 Experimental Procedure

3.4.1 Initial consultation and screening

Interested individuals attended a ‘one to one’ consultation session with the researcher to discuss the requirements of the research, followed by screening for factors which may affect their participation. If the individual was found to meet the study inclusion criteria they were presented with the information sheet. If the potential subject was happy with the requirements of the study, they were issued with a consent form to complete.

The format of the consultation session, which was informed by the feasibility study (chapter 2, section 2.3), was developed to comprise of three main parts. These included detailed explanation and questions, screening (to ensure the subjects did not fit the exclusion criteria), consent and determination of testing dates, in order to standardise the experience for all participants and to ensure all participants received the same information prior to the testing sessions (Figure 3.2).

Part	Agenda
1.	Welcome and brief Information sheet (Appendix 8) and questions Requirements of study (expanded information, Appendix 9) and questions
2.	Screening interview Screening anthropometrics Screening questionnaire (Appendix 6)
3.	Consent form (Appendix 11) Testing dates

Figure 3.2 Format of consultation sessions.

Part 1: Explanation and Questions

On arrival, individuals were formally welcomed. They were first asked if they were clear about what participation in this study would entail based on the information sheet (which had been sent to them prior to the consultation session) (Appendix 8). Potential subjects then had the opportunity to ask questions about the study. A detailed breakdown of specific requirements (Appendix 9) was presented to individuals, with time allowed for questions.

Part 2: Screening

1) Screening interview:

To determine if potential subjects met the study inclusion/exclusion criteria, they went through an informal screening interview which consisted of a series of questions regarding;

- Date of birth
- Allergies/ aversions to test ingredients
- Presence of any illness (as this may affect appetite)
- Medications which may affect appetite
- Prescription of / adherence to any therapeutic diets/ dietary plans
- Presence of any metabolic disorders
- Presence of dentures

2) Screening anthropometric measurements:

The researcher measured each individual's height (m), and weight (kg) in order to determine their BMI (kg/m^2). Height (m) was measured using a fixed wall mounted stadiometer (Charder HM200 PW, wall mounted stadiometer). Individuals were asked to remove their shoes and stand, feet together, with their heels, buttocks and back touching the stadiometer. Measurements were taken at the end of an inward breath as per the ISAK guidelines (Stewart et al. 2011).

Weight (kg) was measured using digital scales (Salter, Model 9010). Heavy clothing and shoes were removed prior to taking the measurement. BMI was calculated using the standard formula ($\text{weight (kg) / height (m}^2\text{)}$) (WHO report 1998). Those found to have a BMI value $>30\text{kg/m}^2$ were excluded as individuals classed as obese may have altered appetite responses (Arora 2006), and increased energy requirements (chapter 2, section 2.1.2).

3) Screening questionnaire

Potential subjects were then issued a questionnaire which aimed to measure their dietary restraint (Stunkard and Messick 1985). Dietary restraint refers to the tendency to restrict food intake in order to control bodyweight. If individuals who demonstrated this behaviour were included in the study, the research outcomes could become biased due to a conscious decision to limit food intake, followed by a possible period of binge eating (Chambers and Yeomans 2011), thereby neglecting true feelings of appetite.

The questionnaire issued to measure this behaviour was the restraint factor of the Three Factor Eating Questionnaire (TFEQ) (Appendix 6). This was developed by

Stunkard and Messick (1985) and has been validated and shown to have good test reliability (Laessle et al. 1989). It is a questionnaire that is used extensively in appetitive research to determine eating behaviour (Allison and Baskin, 2009). The questionnaire was self-administered and consisted of 21 true/false, and most appropriate answer, style questions. A threshold score (>13) was used as the cut off score which is suggestive of high dietary restraint. No lower cut-off threshold score is advised (Stunkard and Messick, 1985).

Part 3: Consent form and testing dates

If individuals were found to meet the inclusion criteria they were formally asked if they would like to take part in the study, while being informed that they were under no obligation to do so and could also withdraw from the study at a later date should they wish to. Those who decided to take part were asked to provide written informed consent. One or more testing days were then arranged with the researcher.

Inclusion of a wash out period is not specifically outlined in the report which describes the set of scientific procedures used to assess the impact of foods and food ingredients on the expression of appetite (Blundell et al. 2010). However in the current study there was to be a “wash out period” of a minimum of three days between each testing session. This was imposed as all test meals used in the testing sessions were to be a cottage pie, and although each meal varied in characteristics (texture and/or energy density) consecutive exposure may have resulted in fatigue to this meal.

It is not standard practice to imply a “wash out period” in appetite research studies with some studies not even considering it as part of the experimental design (Mattes 2006; Norton et al. 2006b; Mattes and Campbell 2009). Others do include a minimum time periods to lapse between sessions however these vary greatly, from ≥ 1 day (Marcini et al. 2001; Devitt and Mattes 2004; Zijlstra et al. 201), to 14 days (Bell et al. 1998). Most similar experimental appetite studies do not state a maximum lapse period between testing sessions (Mattes 2006; Norton et al. 2006b; Marcini et al. 2001; Devitt and Mattes 2004; Mattes and Campbell 2009; Zijlstra et al. 2011) although some tend to impose a testing sequence following the format of “once per week for a particular period of weeks” (Rolls et al. 2004; Flood and Rolls 2007; Flood-Obbagy and Rolls 2009; Blatt et al. 2010).

No maximum limit between testing dates was imposed (although was recorded). However it was implied during recruitment that passage throughout the research protocol (*i.e.* from initial contact, to receipt of the fourth day of the diet diary) would be completed within a maximum period of six months. To ensure compliance to the procedures, subjects were reminded of the research protocol prior to each session and guided through each testing session by the researcher.

3.4.2 Testing session procedure

On the day prior to the session, the researcher began to prepare the meat base for the test meal which was stored in the refrigerator (4° C) overnight. Weight (g) measurements were recorded at every stage of preparation to ensure accuracy of preparation, and thus the yield. This would enable accurate determination of the

amount of product consumed at the sessions using the plate wastage method (Williams and Walton 2011). Prior to the session on the testing day, the researcher completed preparation of the pie by preparing the potato topping followed by the final stage of cooking. A complete description of the method for meal production can be seen in Appendix 3 (a-d).

Participants were required to attend a total of four individual one hour testing sessions where they were presented with one of four versions of the meal in a randomised order (section 3.2). In order to standardise the procedures, on the morning of the test days, participants were instructed to consume and record their regular breakfast (before 8.30 am) and then to fast (water was permitted) for at least four hours prior to the lunch time testing session (12.30 pm). This was to ensure participants attended the feeding session in a similar state of hunger on each occasion. Their regular breakfast was consumed in order to maintain habitual intake, however this same breakfast was consumed for each of the four test days. The period of fasting was not considered to be harmful due to its relatively short duration, and that it represents the usual period between breakfast and lunch.

Participants were also asked to abstain from alcohol consumption and strenuous exercise on the day prior to, and also on the testing days as varying these conditions could confound the results (chapter 2, section 2.1.2). Smoking and coffee drinking were not permitted in the hour prior to the testing session as these may affect appetite and sensory perceptions (Mineur et al. 2011; Carter and Drewnowski 2012).

Participants entered the laboratory in a fasted state after consuming their standard breakfast at least four hours prior to the testing session. Tables were arranged in rows

in order for participants to be sat separately so as to avoid communication between participants which may have affected appetite ratings and food intake (chapter 2, sections 2.1.1 and 2.1.2). On each participant's desk, there was a glass (200 ml volume), a jug was also to be measured) a white plate (18cm), a set of cutlery (knife and fork) enclosed in a plain napkin, a pen, a copy of the workbook containing the visual analogue scales (Appendix 12), and a sheet reiterating the outline of the testing session (chapter 2, section 2.3) (Appendix 13).

Once participants had settled in their designated seats they were asked to rate their baseline appetite ratings (hunger, fullness, desire to eat) before they had seen the test meal. Feelings of appetite were rated using 100 mm Visual Analogue Scales anchored at each end with descriptive extremes. For example for the question; '*how hungry do you feel?*' the scale was anchored with "not at all" on the left hand side, and "extremely" on the right hand side. Participants were required to mark a point on the scale within the anchored points which related to how they felt for each question.

They were then asked to self-serve an unlimited serving of the test meal and before tasting the meal, were asked to rate their appetite responses as before. This was to assess the visual and aromatic affects the meal had on the appetite responses. When the meal had sufficiently cooled to a comfortable eating temperature, participants were instructed to take one mouthful of the test meal and to then rate their appetite (hunger, fullness and desire to eat), as well as to rate the palatability of the test meal. After that, participants were free to consume the meal as they would naturally and were required to answer the remaining questions at ten minute intervals as alerted by the researcher. When participants felt that they had reached satiation, they notified the researcher after which their plate, dish and cutlery were taken away.

The time that satiation (*i.e.* meal termination) was reached was recorded by the researcher in order to later calculate the period of satiety (*i.e.* time until the next eating occasion) (as recorded in the provided diet diaries (Appendix 10) by the participants). Participants were not specifically aware that ad libitum intake was an outcome measure of the study as knowing that could have affected the study outcomes by causing subjects to alter their eating behaviour (chapter 2, section 2.1.2). Regardless of their state of satiation (*i.e.* whether or not they had finished ad libitum consumption of their meal) participants were required to stay until the end of the session and to answer all the questions in the workbook relating to appetite and palatability. In total, their appetite responses were measured nine times over a one hour period.

Once the participants had vacated the laboratory, the researcher weighed the remains of the test meal in order to quantify the amount (g) of the test meal needed to reach satiation. This was done using a plate wastage method (Williams and Walton, 2011). The researcher also separated the remains of the pie into its individual components; meat base (beef, carrots, mushroom, etc.) and potato topping, in order to calculate a more accurate energy intake (kcal) consumed, as these components differed in energy density (chapter 2, section 2.2.2, Table 2.7). For the rest of the day, participants were required to continue to keep a record of their dietary intake and time of consumption in a food diary sheet. An overview of the testing day can be seen in Figure 3.3.

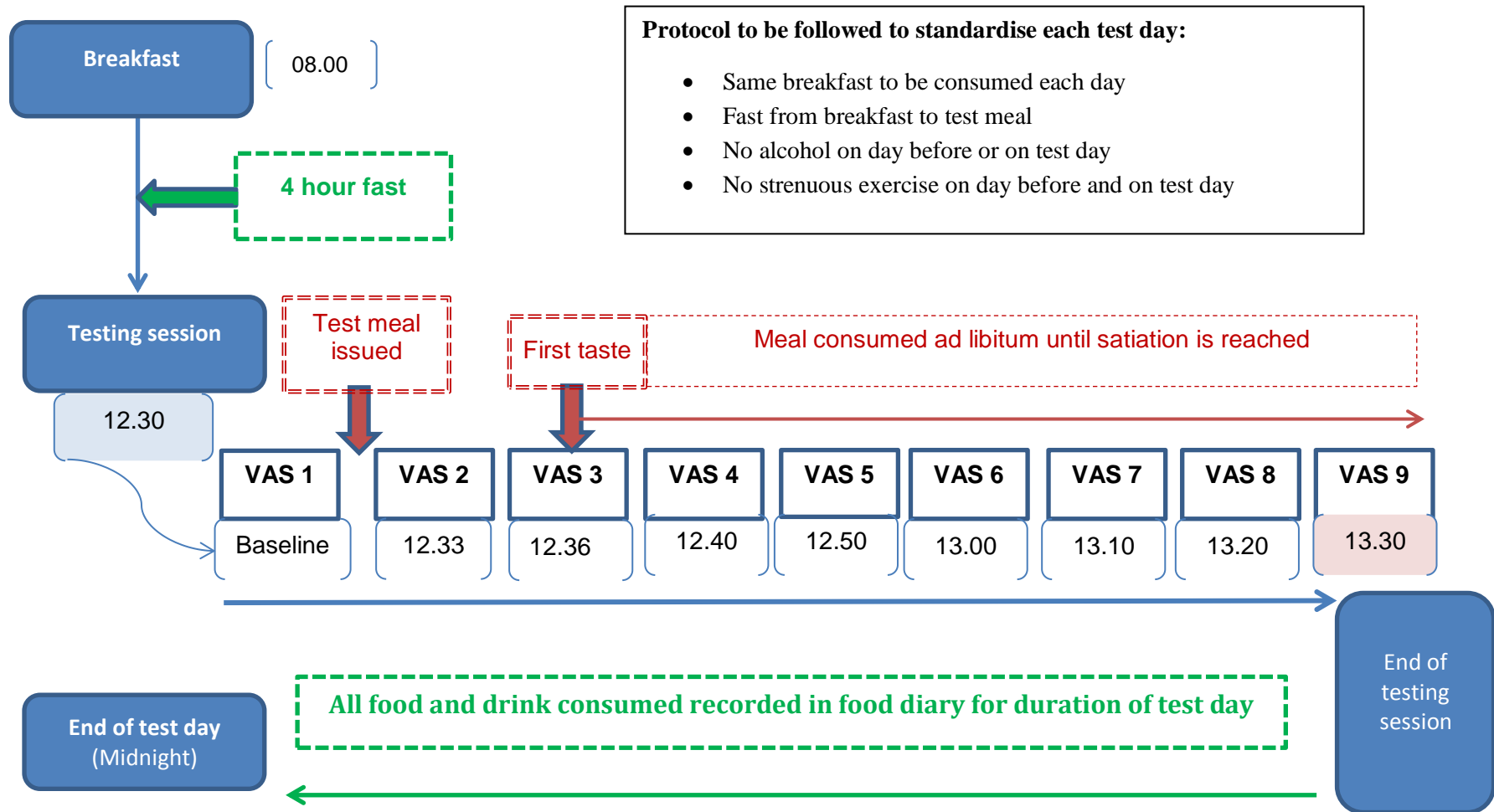


Figure 3.3 Outline of a test day for participants

3.5 Outcome Measures

3.5.1 Ad libitum food (g) and energy (kcal) intake at test meal

Ad libitum food intake (measured in grams) of the meal consumed at the testing session was the primary outcome measure, and is a standard method used for measuring the satiating qualities of foods (Benelem 2009; Alison and Baskin 2009; Blundell et al. 2010). Ad libitum food intake was determined using a plate wastage method (Williams and Walton 2011) where the quantity of food necessary to reach satiation was recorded, and was directly compared for all four meal conditions (Figure 2.2).

Energy intake (kcal) consumed at the testing sessions was estimated from ad libitum food intake (g) by separating and weighing the remaining meal components (potato topping and meat base) to determine the quantity of each constituent of the pie that was consumed. Using this information the energy intake (kcal) that was consumed was calculated using a specifically designed database in Microsoft Excel (2010), incorporating the energy density of each of the individual pie components.

The quantity of each macronutrient consumed at the test meal was estimated by calculating the quantity of each macronutrient present in 1g of the test meal. Again, the meat and potato component of the pie were analysed separately. These values were then multiplied by the quantity of test meal components (meat base and potato top) that were consumed. Total quantity of macronutrient consumed at the test meal was then calculated by adding the values obtained from the meat base and the potato top. This was carried out for fat, protein and carbohydrate.

3.5.2 Daily energy intake (kcal)

Daily energy intake (kcal) was a secondary outcome measure. Subjects were permitted to consume food and drink freely once they had left the testing session but were required to describe and record details including the time of any food and beverage consumption on the testing day. This included food consumed prior to the testing session which allowed the researcher to ensure that participants had fasted sufficiently prior to the session. It also enabled the determination of satiety (*i.e.* by quantifying the time (minutes) between finishing the test meal (satiation) until the participants next eating occasion (>100 kcal)) (sections 3.5.6 and 3.6.4).

Prior to commencing the study, subjects were instructed how to record their food intake using an estimated food diary. Information to help estimate portion sizes was provided (Appendix 10) in order to ensure greater accuracy in the recording of consumed quantities of food. Diet diaries were returned to the researcher in person at a following testing session or else returned via post where a self-addressed, franked envelope was supplied (especially in the case of the last testing day). During analysis, the researcher checked the diet diaries for completeness. Follow up phone calls were made to clarify any unclear information such as food brands and portion sizes when necessary.

The diet record method is a valid method for assessing dietary intake which requires the respondent to record the quantity and time of consumption of all foods and beverages over a defined period of time. A weighed food record is the most precise method available for estimating usual food intakes of individuals (Gibson 2005) and is considered the ‘gold standard’ in dietary assessment (Thompson and Subar 2008).

Estimated (non-weighed) food records have however been successfully previously used in comparison studies of dietary assessment methods (Comrie et al. 2009). The non-weighed (estimated) food diary was chosen over the weighed diary in this study to reduce participant burden and facilitate recruitment.

Despite its popularity for assessing dietary intakes, the diet diary does have limitations which must be acknowledged. Dietary record keeping requires that respondents be both motivated and literate, which can potentially limit use of this method in some population groups (Thompson and Subar 2008). Furthermore, maintaining diet diaries tends to interfere with the daily lives of subjects, altering dietary habits so that they no longer represent true habitual intake. This is however less observed with the use of estimated food records compared to weighed food records (Wrieden et al. 2003). Despite its limitations, the food diary is a quick, cheap and uncomplicated method which is successfully used to measure dietary intake. In this study, participants were required to keep four individual one day diet diaries with a minimum of three days in between each test day to avoid testing fatigue and the potential of a confounding carryover effect.

To estimate daily energy intakes; breakfast energy intakes and post-test meal energy intakes (as recorded in the subjects' food diaries) were calculated using the nutritional analysis programme "WinDiets" (WinDiets 2005: Robert Gordon University, Aberdeen, UK). The energy consumed at the test meal was then added to this to yield total daily energy intakes (kcal).

3.5.3 Post-meal intake:

Using the information provided in the diet diaries, post-meal energy (kcal) and macronutrient (protein (g), fat (g), carbohydrate (g)) intakes were assessed in order to later calculate the impact of the test meal alterations on compensation (section 3.5.7). These were calculated separately for each individual by subtracting both the intakes at breakfast and the intakes at the test meal from the daily intake values.

For example: Post-meal intakes = Daily intakes – (test meal intakes + breakfast intakes).

Estimating the accuracy of participants dietary reporting

To investigate the validity of the diet reporting method used (diet diaries), predicted energy requirements (energy expenditure (EE)) were compared to calculated intakes from the diet diaries. Predicted energy requirements were calculated by first estimating each individual's basal metabolic rate (BMR). This value was then multiplied by a physical activity level (PAL) value as $EE = BMR \times PAL$. BMR was not directly measured in this study therefore it was estimated. This was done using the Henry (Oxford) equations (Henry 2005), as these are the most accurate methods for estimating BMR indirectly in a healthy population (SACN 2010). Based on the Henry (Oxford) equations (Henry 2005) BMR was determined using the following equation;

$$BMR = \text{weight coefficient} \times \text{weight (kg)} + \text{height coefficient} \times \text{height (m)} + \text{constant}.$$

Both the weight and height coefficients, as well as the constant value, varied depending on the age and gender of the individual. These were attained from the SACN report describing the derivation of the updated dietary reference values for energy (SACN 2010, Appendix 14). The values for weight (kg) and height (m) which had been determined during the screening consult (section 3.4.1) also varied for each participant

To determine EE, a PAL factor needed to be established. It was decided to follow guidance from the SACN report for defining the PAL factor for use in the current study. The PAL factor of 1.63 was chosen as this has been identified as the median PAL value for a population with similar characteristics to the UK population. Although participants were asked to refrain from strenuous exercise on the day of, and the day prior to the testing sessions, a PAL value of 1.63 is likely to be accurate for a healthy population going about the normal activities of daily living. It would be misleading to use a lower PAL value (*i.e.* one relating to less active behaviour (PAL <1.49 (SACN 2010))), as the sample group included those who were healthy and mobile.

Energy expenditure was however not measured therefore this assumption may not be entirely accurate. Further, the lifestyles of the individuals recruited may differ and therefore a PAL value of 1.63 may not accurately apply to every individual in the study. Using a PAL that was too high would falsely show a high level of under reporting, whilst using a PAL that was too low would falsely suggest a high level of over reporting. It was thought that using the median value, would apply to the

majority of the population, and thus was assumed to be the best value to use in the current study.

The determined value for EE using the Goldberg method ($\text{BMR} \times \text{PAL}$) (Goldberg et al. 1991) was compared with the daily energy intakes estimated from the participants' diet diaries to identify discrepancies in the values potentially denoting misreporting. A negative value denoted an individual may have under reported, whereas a positive value denoted an individual may have over reported. These values must however be interpreted cautiously (chapter 5, section 5.2).

3.5.4 Appetite sensations and palatability assessed using VAS

Participants were issued a workbook (Appendix 12) to be completed at each testing session, which contained nine questions consisting of visual analogue scales (100 mm anchored VAS). The scales were used to allow participants to rank their feelings of hunger, fullness, desire to eat, and the palatability of the meal.

Ratings were assessed when participants entered the testing sessions to assess baseline appetite ratings. Participants were then asked to rate the different parameters after they had served their meal but before their first mouthful to measure if the visual and aromatic aesthetics of the food have an effect on hunger and desire to eat. Once participants had tasted the meal, they were asked again to rate the appetite attributes, and then again at 10 minute intervals for the one hour feeding session.

3.5.5 Period of time taken to consume meal to satiation:

The researcher recorded the time that each participant took to consume the test meals to the point of satiation. To determine the time that it took for each meal to be consumed, the start time of the testing session was subtracted from the time that satiation was reached.

3.5.6 Period of satiety

On each of the testing days, participants were asked to record the time of any food consumption, including food consumed prior to the testing session within the food diary provided. This allowed the researcher to determine the longevity of the satiety effect of the meal in its different conditions, by calculating the time that passed (minutes) from when satiation was reached (section 3.5.1) until the time that the next eating occasion was initiated (diet diary). This also allowed the researcher to assess compliance to the research protocol surrounding standardised breakfasts followed by fasting prior to the test meal.

3.5.7 Energy compensation

To determine energy compensation, COMPX scores are calculated by dividing the difference in energy intake after two preloads by the difference in energy content of the preloads, transformed to a percentage (Johnson and Birch 1994).

The formula for determining COMPX can be seen below:

$$COMPX = \frac{(\text{post preload energy intake (1)} - \text{post preload energy intake (2)})}{(\text{preload energy intake (2)} - \text{preload energy intake (1)})}$$

(Johnson and Birch 1994)

Researchers have implemented this type of calculation to assess energy compensation in both experimental and clinical situations, in children (Cecil et al. 2005; Johnson and Taylor-Halloway; 2006; Kane et al. 2011) and adults (Appleton et al. 2011; Jokisch et al. 2012). Using the formula above the reciprocal relationship between energy consumed as a preload and energy consumed after the preload can be determined.

Appleton et al. (2011) altered the calculation slightly and also determined the percentage compensation. Energy compensation was calculated by dividing the difference in energy intake at the two test meals, by the difference in energy content of the two preloads and multiplying by 100 to provide percentage compensation. Here, authors interpreted that where 100% compensation represents perfect compensation, <100% represents incomplete compensation and >100% represents overcompensation. Accuracy of energy compensation was calculated as difference from 100% compensation, regardless of direction (Appleton et al. 2011). The calculation used by Appleton et al. (2011) can be seen below.

$$COMPX \% = \frac{(\text{energy intake test meal 1} - \text{energy intake test meal 2})}{(\text{energy intake preload 1} - \text{energy intake preload 2})} \times 100$$

(Appleton et al. 2011).

The two previous formulas however are dependent on the use of a test meal and a pre-load meal. In the case of the current study essentially the test meal is the pre-load and will not be consumed in a fixed amount among all participants. Therefore the amount of energy consumed at the test meal will vary for each individual. Intakes prior to the test meal were not considered in the calculation as protocol dictated that intakes mimic habitual intake and standardise hunger states/ energy intakes prior to the test meal. Intakes prior to the preload are not considered when calculating energy compensation (Cecil et al. 2005; Johnson and Taylor-Halloway 2005), with calculations focussing only on the preload of interest and all subsequent intakes.

Therefore, considering the design implemented in this study, energy compensation was calculated using the following formula;

% ***Energy compensation***

$$= \frac{(\text{post test meal energy intake (meal 1)} - (\text{post test meal energy intake (meal 2)})}{(\text{test meal energy intake (meal 2)} - \text{test meal energy intake (meal 1)})} \times 100$$

Where for:

Standard texture meals

Post-test meal energy intake (meal 1)= ST ED

Post-test meal energy intake (meal 2)= ST SE

Test meal energy intake (meal 1)= ST ED

Test meal energy intake (meal 2)= ST SE

Texture modified meals

Post-test meal energy intake (meal 1)= TM ED

Post-test meal energy intake (meal 2)= TM SE

Test meal energy intake (meal 1)= TM ED

Test meal energy intake (meal 2)= TM SE

In the case of the current study, the “test meal” took the place of the usual “pre-load meal”, whereas the “post-test meal energy intake” replaced the usual “test meal”. In

other words, the difference in post-meals energy intake was being divided by the difference in energy content consumed at the test meal. This was then transformed to a percentage.

The resulting “% compensation” gave the difference between meal conditions in energy (kcal) consumed after the test meal as a percentage of the energy difference between the test meals. No compensation (*i.e.* 0%) indicated that subjects did not compensate at all for the test meal energy difference, and 100% compensation suggests that the subjects compensated completely for the energy difference between meal conditions. Compensation values >100% indicated that subject overcompensated, whereas compensation values between 1% and 99 % indicated that subjects compensated incompletely.

3.6 Data Analysis:

Raw data were manually entered into one of two relevant specifically designed databases (as informed by feasibility study (chapter 2, section 2.3). Food weight (g) calculations were performed in a specifically developed Excel database to determine ad libitum food intake (g), and ad libitum energy intake (kcal). This data was then transferred to the main database (SPSS for windows (v. 19.0, 2011 SPSS Inc. Chicago, IL)) where comparisons were made. Data were analysed using SPSS for Windows (version 19.0, 2011 SPSS Inc. Chicago, IL).

Data were checked for normality using the Shapiro-Wilk test, with p values >0.05 suggesting that data were normally distributed. These tests revealed that the majority

of data followed the required normal distribution therefore ANOVA was performed using the general linear models procedure. Values reported are mean and standard deviations (SD) unless reported otherwise. Results were considered significant if $p < 0.05$. P- values were explicitly reported within the text, however where $p = 0.000$, $p < 0.001$ was stated. Where ANOVA detected significant differences, post-hoc analysis (unadjusted) was performed to identify between which conditions differences existed.

This research was investigating specific research questions with clear rationale (chapter 1, section 1.7) with a modest number of comparisons ($n=12$). Thus it was felt not to be necessary to adjust (with Bonferroni) during the post hoc comparisons. There is in fact no formal consensus for when Bonferroni procedures should be used, even among statisticians (Perneger 1998). There is a logically incorrect belief that results are in fact “more significant” if they pass the rigour of Bonferroni corrections (Nakagawa 2004). In fact, when Bonferroni adjustments are made likelihood of type II errors is increased, so that truly important differences are deemed non-significant (Perneger, 1998).

3.6.1 Food intakes

Food (g) energy (kcal) and macronutrient intakes consumed at the testing session were compared using repeated-measures ANOVA to compare means and evaluate differences for each individual across the four meal conditions (chapter 2, Figure 2.2). To determine interactions between texture and energy density on food (and

resulting consumed energy intakes) at the testing sessions, two-way Repeated Measures ANOVA was used.

3.6.2 Daily energy and macronutrient intakes

Daily energy and macronutrient intakes were compared using repeated-measures ANOVA to compare means and evaluate differences for each individual across the four meal conditions (Figure 2.2). Where ANOVA detected significant differences, post-hoc analysis (unadjusted) was performed to identify where these differences exist. Correlation analysis using Pearson's product-moment correlation coefficient (r) was adopted to determine the relationship between test meal energy intake and daily energy intake.

3.6.3 Appetite and palatability ratings

Appetite ratings (hunger, fullness, desire to eat and palatability) from the completed VAS questionnaires were quantified by the researcher by measuring the distance from the left end of the line to the participants' mark to the nearest millimetre using a ruler. As the appetite ratings (mm) from the VAS were found to be non-normally distributed, they were analysed using Friedman's ANOVA to investigate whether there was a change in participant rated appetite scores over the study period, detecting main effects for time within participants.

The area under the curve (AUC) for each appetite time-profile (hunger, fullness, desire to eat and prospective consumption) was calculated using the Trapezoid Method, which involved dividing the area between the curve and the x-axis into a number of trapezoids, calculating the area of each and summing these values to obtain total AUC. Use of the AUC allowed each participant's appetite ratings over the one hour testing period to be reduced to a single figure thus enabling relationships between test meal intake (g, and kcal) and appetite to be assessed.

AUC data was found to be parametric and normally distributed, thus Pearson's product-moment correlation coefficient (r) was adopted to assess relationships between appetite and food intakes. Individual correlation analyses were performed between the amount of a test meal consumed and its rated palatability, as well as participants' desire to eat, their fullness and their hunger ratings. These correlations aimed to further investigate if alterations in energy density and food form (texture) impacted on appetite and food intake. To assess any difference in appetite profiles between the meal conditions, comparisons of the AUC for each of the appetite parameters were carried out using RM ANOVA.

3.6.4 Period of satiety

Period of satiety was quantified by determining the time (min) between when subjects reached satiation during the test lunch until the next eating occasion which was defined as >100 kcal (Mattes and Campbell 2009). Times (min) between

satiation until the next eating occasion for each condition were compared using RM ANOVA.

3.6.5 Time (mins) to consume the test meal until the point of satiation.

The time (mins) taken to consume the test meal until the point of satiation (*i.e.* termination of the test meal) was compared using RM ANOVA to determine any differences between meal conditions.

Chapter 4:

Results

4.1 Subjects

4.1.1 Subject characteristics

A full overview of the flow of participants through the study from recruitment to enrolment can be seen in Figure 3.1 (chapter 3). Thirty seven individuals who had expressed interest and had passed the screening interview (by telephone) attended a consultation session at QMU. Of the 37 individuals who expressed interest, four individuals could not participate (one subject was taking medication known to affect appetite, two subjects had metabolic disorders and were also classed as obese, and one subject could not commit to the four study dates) therefore these individuals did not enrol in the study (Figure 4.1).

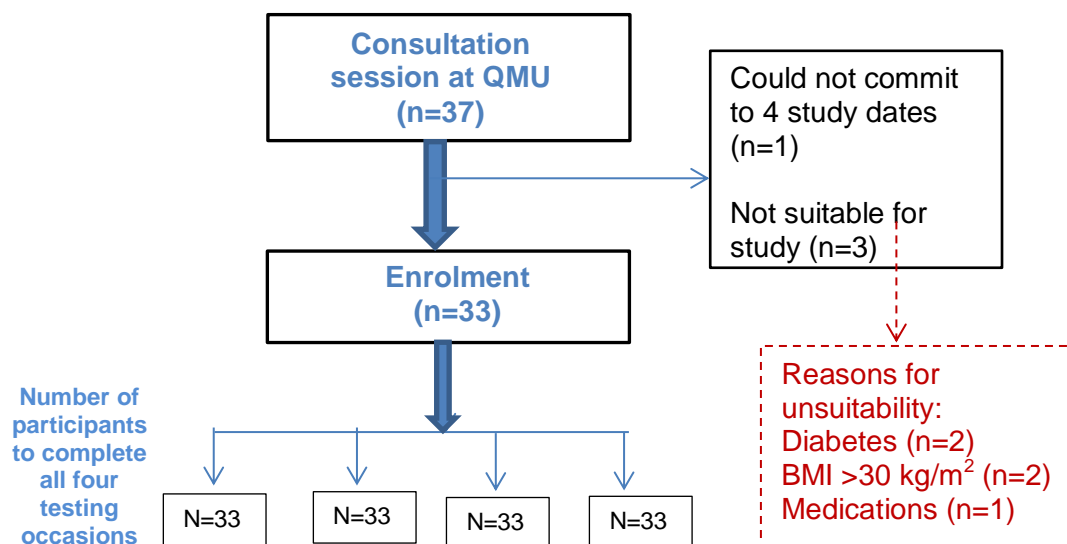


Figure 4.1: Overview of participants through trial

On four test days, each separated by at least 3 days and not greater than six weeks (median, (IQR) 7 (7,14) days) subjects attended the testing sessions. The median (IQR) total period for the study (from test day 1 to test day 4) was 29 (21, 35) days. No subjects dropped out of the study after enrolment and therefore the final sample consisted of n=33 adults (Table 4.1).

All subjects were healthy, non-obese and reported to generally like the test meal. Smokers (n=3) were included in the study but were required to refrain from smoking at least one hour prior to the testing session. Of these three subjects, two reported to smoke occasionally (<5 per week), whilst one subject reported to smoke more than five cigarettes per day.

Table 4.1 Subject characteristics (Mean \pm SD) (n=33).

Subject characteristics	Mean \pm SD	Range
n	33	10 males, 23 females
Age (years)	46.5 \pm 18.1	22-77 years (52 % <50 years, 48% >50 years)
Height (m)	1.66 \pm 0.1	1.48- 1.92 m
Weight (kg)	66.9 \pm 13.5	45.8- 100.4 kg
BMI (kg/m ²)	24.0 \pm 3.3	18.76- 29.61 kg/m ²
TFEQ (restraint)	6.0 \pm 3.3	0-13 TFEQ score

4.2 Food (g) and fluid intake (ml)

4.2.1 Test meal food intake (g)

Food intake (g) at the testing session significantly differed between the test meals (F_(3, 96) = 4.232, p=0.007) (Table 4.2). Post hoc analysis revealed that food intake (g) at

the test meal was reduced with texture modification for both the SE ($p=0.014$) and ED ($p=0.034$) meals. A two factor ANOVA incorporating the effect of both texture and energy density detected that texture had a significant effect on food intake at the test meal ($F_{(1,32)} = 10.894$, $p=0.002$), reducing intakes by 9% (66 g (SE)) and 7% (51 g (ED)). Energy density did not have a significant effect on food intake ($p=0.847$) nor was there an interactive effect of texture * energy density ($p=0.661$).

Table 4.2 Mean (SD) food (g) and energy (kcal) intakes

Meal	Test meal intakes (g)	Test meal energy intake (kcal)	Post-test meal energy intakes (kcal)	Daily energy intakes (kcal)
ST SE	745 +/- 228	709 +/- 220	906 +/- 356	1888 +/- 493
95% C.I	664 - 825	630 - 787	780 - 1032	1713 - 2063
ST ED	734 +/- 231	1024 +/- 317 ^a	858 +/- 376	2148 +/- 561 ^a
95% C.I	652 - 816	911 - 1136	725 - 992	1949 - 2347
TM SE	679 +/- 231 ^{a,b}	648 +/- 222 ^{a,b}	971 +/- 375	1888 +/- 489 ^b
95% C.I	597 - 761	569 - 727	838 - 1104	1715 - 2061
TM ED	683 +/- 230 ^{a,b}	951 +/- 318 ^{a,b,c}	904 +/- 404	2113 +/- 559 ^{a,c}
95% C.I	602 - 764	838 - 1063	760 - 1047	1915 - 2311

Significant differences ($p<0.05$): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE
One way RM ANOVA
n=33

4.2.2 Fluid intakes (ml) at each test meal occasion

Mean fluid (water) intakes (ml) (Figure 4.2) did not differ between test days ($p=0.407$). Mean (SD) intakes across all of the four meal occasions (*i.e.* the grand mean) were 233 (10) ml, (95 % C.I: 198-268 ml).

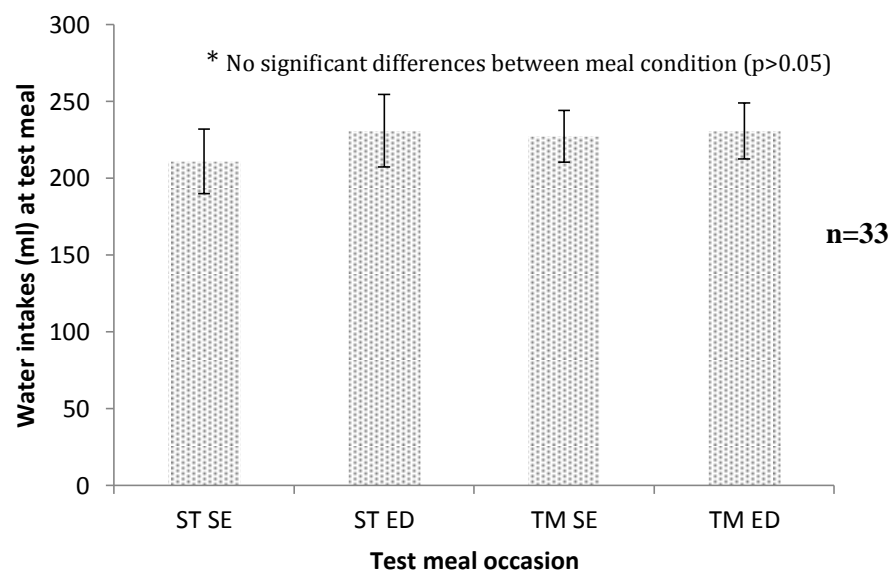


Figure 4.2: Mean (standard error) water intakes (ml) at each test meal occasion

4.3 Energy (kcal) and nutrient (g) intakes

4.3.1 Breakfast energy and macronutrient intakes

Mean energy intakes (kcal) at breakfast (Figure 4.3) did not differ between treatment days ($F_{(3, 96)} = 1.936$, $p=0.129$). Breakfast intakes of all of the macronutrients; protein ($F_{(3, 30)} = 1.333$, $p=0.282$), carbohydrate ($F_{(3, 30)} = 1.379$, $p=0.268$) and fat ($F_{(3, 30)} = 1.6661$, $p=0.196$) were not significantly different.

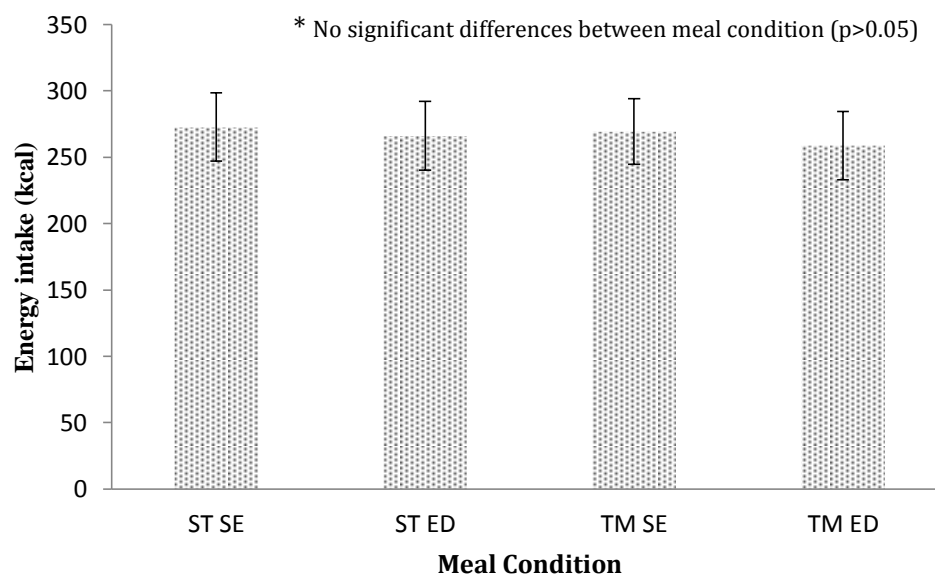


Figure 4.3 Mean (standard error) energy intakes (kcal) at breakfast (n=33)

4.3.2 Breakfast micronutrient intakes:

Overall, there were no significant differences for all micronutrients intakes consumed at breakfast between the test days (Table 4.3). Post hoc tests revealed that intakes of zinc (Zn) and calcium (Ca) were however significantly lower (Ca: 8 mg, Zn, 0.06 mg) on the day the TM ED was consumed compared to the day of the ST ED meal was consumed. A full breakdown of micronutrient (mean (SD)) intakes consumed at breakfast for each test day can be seen in Table 4. 3.

Table: 4.3 Mean (SD) Breakfast micronutrient intakes

Nutrient	ST SE	ST ED	TM SE	TM ED
Vitamin A (ug)	71(229)	71 (229)	72 (229)	68 (230)
B12 (ug)	0.79 (0.79)	0.79 (0.78)	0.77(0.76)	0.76 (0.75)
Folate (ug)	67 (63)	66 (63)	64 (63)	63 (64)
Vitamin C (mg)	35 (80)	33 (81)	33 (80)	33 (81)
Vitamin D (ug)	0.02 (0.07)	0.02 (0.07)	0.02 (0.07)	0.02 (0.07)
Calcium (mg)	169 (105)	169 (107)	165 (104)	162 (107) ^b
Na (mg)	241 (237)	244 (238)	233 (238)	237 (241)
K (mg)	590 (516)	598 (528)	545 (514)	574 (517)
Fe (mg)	2.5 (2.2)	2.5 (2.1)	2.4 (2.1)	2.3 (2.1)
Zn (mg)	1.12 (0.67)	1.15 (0.69)	1.13 (0.64)	1.09 (0.66) ^b

Significant differences (p<0.05): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE
 One way RM ANOVA

4.3.3 Test meal provisions:

As dictated by the research protocol for test meal provision (chapter 2, sections 2.1.1. and 2.1.2) the absolute weight of test meal provided did not differ between the testing sessions (Table 4.4). However, due to the altered energy density the enriched test meals provided a significantly greater opportunity to consume more energy per weight of meal consumed.

Enriching the meal further altered the micronutrient content of the meal (Table 4.4). Compared to the standard energy meals, the enriched meal had significantly less vitamin A (ST: 148 ug, $p<0.001$ TM: 151 ug, $p<0.001$), folate (ST: 4 ug, $p<0.001$, TM: 6 ug, $p<0.001$), calcium (ST: 56 mg $p<0.001$, TM: 45 mg, $p<0.001$) and potassium (ST: 46 mg $p<0.001$, TM: 55 mg $p<0.001$). However the enriched meal had provided significantly more vitamin B₁₂ (ST: 0.3 ug $p<0.001$, TM: 0.4 ug, $p<0.001$), vitamin D (ST: 0.1 ug $p<0.001$, TM: 0.1 ug, $p<0.001$) sodium ST: 129 mg $p<0.001$, TM: 127 mg, $p<0.001$) and zinc (ST: 0.2 mg $p<0.001$ TM: 0.3 mg, $p<0.001$). There were no differences in nutrient content of the meals with texture modification.

4.3.4 Test meal energy intakes

Test meal energy intakes were significantly different between meals ($F_{(3, 96)} = 70.675$, $p<0.001$). Post hoc analysis revealed that texture modification resulted in reduced energy intakes at the test meal in both the SE (61 kcal, $p=0.018$) and ED (73 kcal, $p=0.03$) conditions. Despite this, energy intake was significantly greater at the TM ED meal compared to the ST SE meal ($p=0.001$). Energy intakes at the test meal significantly increased with energy enrichment of both the ST ($p=0.001$) and TM ($p=0.001$) meal. Increasing the energy density resulted in test meal energy intakes being increased by 44% (315 kcal) for ST, and 47% (303 kcal) for TM meals.

Two factor ANOVA revealed that texture had a significant effect on energy intake ($F_{(1, 32)} = 10.565$, $p=0.003$). Energy density (1.0 kcal/g vs. 1.4 kcal/g) also significantly affected test meal energy intakes ($F_{(1, 32)} = 162.149$, $p<0.001$). Energy intake was not

affected by texture*energy density ($p= 0.734$). Mean (SD) test meal energy intakes are displayed in Table 4.2.

4.3.5 Test meal macronutrient intakes (g):

Test meal intakes (g) for protein did not differ across test days ($p=0.193$), however both fat and carbohydrate intakes (g) at the test meals were significantly different across test days; carbohydrate: $F_{(3, 30)} = 6.854$, $p=0.001$ and fat: $F_{(3, 30)} = 103.39$, $p<0.001$. Post hoc analysis (unadjusted) revealed that carbohydrate intake was significantly lower when the texture modified meals were consumed in both SE (9 g, $p=0.001$) and ED (7 g, $p<0.001$) versions. Fat intakes (g) were significantly higher on the enriched test meal days for both the ST (35 g, $p<0.001$) and TM (33g, $p<0.001$) versions.

A full breakdown of consumed quantities of the test meal, energy, macronutrient and micronutrients is presented in Table 4.4. Information regarding the amount of each that was provided, and consumed as well as a % of provided is included.

4.3.6 Test meal micronutrient intakes:

Micronutrient intakes consumed at the test meals can be seen in Table 4.4. Significant differences ($p<0.05$) are indicated on the table. Trends relating to the texture or energy density manipulations of the meals were identified. Intakes for Vitamin D were significantly greater with consumption of the enriched meals (ST: 0.07 ug, $p=0.02$, TM: 0.06 ug, $p=0.03$). Calcium intakes were lower with

consumption of the enriched meals (ST: 40 mg, $p<0.001$, and TM: 32 mg, $p<0.001$). Compared to the standard texture meals, potassium intakes were reduced with consumption of the texture modified meals (SE: 223 mg, $p=0.01$, ED: 163 mg $p=0.02$).

Table 4.4: Mean (SD) intakes consumed and provided at the test meals (n=33)

Nutrient	ST SE	ST ED	TM SE	TM ED
Absolute weight (g)				
Provided	1170 (8)	1170 (13)	1171 (9)	1170 (6)
Consumed	745(228)	734 (231)	679 (231) ^{a,b}	683 (230) ^{a,b}
%	64	63	58 ^{a,b}	58 ^{a,b}
Energy (kcal)				
Provided	1120 (8)	1622 (18) ^a	1121 (8) ^b	1620 (8) ^{a,c}
Consumed	709 (220)	1024 (317) ^a	648 (222) ^b	951 (318) ^{a,b,c}
%	63	63	58 ^{a,b}	59 ^{a,b}
Protein (g)				
Provided	70 (0.7)	70 (0.9)	70 (0.5)	70 (0.5)
Consumed	42(14)	42(14)	39(14)	40 (14)
%	60	60	56	57
CHO (g)				
Provided	119 (0.5)	119 (1.5)	119 (1.1)	118 (0.5)
Consumed	76 (20)	74 (21)	67 (22) ^{a,b}	67 (22) ^{a,b}
%	67	66	59 ^{a,b}	60 ^{a,b}
Fat (g)				
Provided	57 (0.5)	105 (1.1) ^a	57 (0.4) ^b	105 (0.5) ^{a,c}
Consumed	27 (9)	62 (19) ^a	25 (9) ^b	58 (19) ^{a,b,c}
%	60	63	57 ^b	58 ^b
Vitamin A (ug)				
Provided	4864 (49)	4716 (71) ^a	4870 (45) ^b	4719 (36) ^{a,c}
Consumed	2885 (1056)	2772 (1015)	2732 (1006)	2654 (945) ^a
%	59	59	56	56
B12 (ug)				
Provided	5.2 (0.05)	5.5 (0.08) ^a	5.2 (0.04) ^b	5.6 (0.04) ^{a,c}
Consumed	3.1 (1.1)	3.2 (1.2)	2.9 (1.1) ^b	3.1 (1.1)
%	60	58	56	55
Folate (ug)				
Provided	282 (1.4)	278 (3.2) ^a	283 (2.4) ^b	277 (1.2) ^{a,c}
Consumed	187 (52)	170 (53)	166 (55) ^{a,b}	165 (54) ^{a,b}
%	66	61	59 ^{a,b}	60 ^{a,b}

Table 4.4 (cont.)

Nutrient	ST SE	ST ED	TM SE	TM ED
Vitamin C(mg)				
Provided	84 (0.8)	84 (1.1)	84 (0.6)	84 (0.6)
Consumed	50 (18)	50 (18)	47 (17)	47 (17)
%	60	60	56	56
Vitamin D (ug)				
Provided	1.34 (0.01)	1.44 (0.02) ^a	1.34 (0.01) ^b	1.44 (0.01) ^{a,c}
Consumed	0.78 (0.29)	0.85 (0.31) ^a	0.75 (0.28) ^{,b}	0.81 (0.29) ^c
%	58	59	56	56
Calcium (mg)				
Provided	236 (1.6)	180 (2.1) ^a	236 (1.7) ^b	181 (1.2) ^{a, c}
Consumed	149 (46)	109 (37) ^a	136 (47) ^{a, b}	104 (17) ^{a, c}
%	63	60	58 ^a	57 ^a
Na (mg)				
Provided	3072 (32)	3201 (42) ^a	3079 (25) ^b	3206 (24) ^{a, c}
Consumed	1807 (675)	1892 (684)	1721 (638) ^b	1809 (641)
%	52	55	49	53
K (mg)				
Provided	3474 (20)	3428 (38) ^a	3479 (27) ^b	3424 (16) ^{a, c}
Consumed	2253(660)	2182 (664)	2030 (684) ^{a, b}	2019 (672) ^{a, b}
%	65	64	58 ^{a,b}	59 ^{a,b}
Fe (mg)				
Provided	8.7 (0.07)	8.7 (0.1)	8.7 (0.07)	8.7 (0.06)
Consumed	5.3 (1.8)	5.3 (1.8)	5.0 (1.8)	5.0 (1.7)
%	61	61	57	57
Zn (mg)				
Provided	13.3 (0.1)	13.5 (0.2) ^a	13.3 (0.1) ^b	13.6 (0.1) ^{a, c}
Consumed	8.0 (2.8)	8.0 (2.9)	7.6 (2.7)	7.6 (2.7)
%	60	59	57	56

Significant differences ($p < 0.05$): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE (One way RM ANOVA)

4.3.7 Post-meal energy and macronutrient intakes

Post-meal energy intakes did not differ between test meals ($F_{(3, 96)} = 0.871$, $p=0.455$). Mean (SD) post-test meal energy intakes are displayed in Table 4.2. Post-meal intakes did not significantly differ for any of the macronutrients (protein ($F_{(3, 30)}=0.816$, $p=0.495$), carbohydrate ($F_{(3, 30)} = 0.583$, $p=0.631$) and fat ($F_{(3, 30)} = 1.521$, $p=0.229$)). Mean (SD) post-meal macronutrient intakes can be seen in Table 4.5.

Table 4.5: Mean (SD) post-test meal macronutrient intakes (n=33)

	Protein (g)	Carbohydrate (g)	Fat (g)
ST SE	42 (35)	121 (66)	36 (20)
ST ED	36 (19)	132 (93)	34 (19)
TM SE	42 (24)	125 (60)	44 (29)
TM ED	42 (25)	124 (68)	36 (20)

No significant differences exist

4.3.8 Post-meal micronutrient intakes:

There were no significant differences observed between all individual micronutrient intakes consumed after the test meal (*i.e.* post-test meal) between the test days (Table 4.6). However post-hoc analysis revealed that zinc intakes consumed post-test meal were significantly higher (0.71 mg) on the day the TM SE meal was consumed compared to the day the ST SE meal was consumed.

4.3.9 Daily energy intakes

Daily energy intakes were significantly different across meal conditions ($F_{(3, 96)} = 6.339$, $p < 0.001$). Post-hoc analysis revealed that daily energy intakes were significantly higher on the days that the ED meals were consumed at lunch for both ST ($p=0.001$) and TM ($p=0.003$) conditions. Increased daily energy intakes of 14 % (260 kcal) for ST, and 12% (225 kcal) for TM meals were observed. Mean (SD) daily energy and macronutrient intakes are displayed in Tables 4.2 and 4.8 respectively.

Table: 4.6 Mean (SD) Post-meal micronutrient intakes

Nutrient	ST SE	ST ED	TM SE	TM ED
Vitamin A (ug)	514 (646)	478 (556)	526 (495)	1452 (5138)
B12 (ug)	2.6 (4.3)	1.7 (1.5)	1.6 (1.6)	6.2 (21.8)
Folate (ug)	106 (68)	107 (64)	106 (72)	126 (90)
Vitamin C (mg)	74 (83)	59 (64)	56 (58)	63 (58)
Vitamin D (ug)	1.17 (1.88)	0.92 (1.31)	1.16 (2.48)	2.34 (8.27)
Calcium (mg)	322 (200)	250 (247)	248 (212)	362 (230)
Na (mg)	889 (607)	1184 (922)	1124 (761)	1151 (614)
K (mg)	1517 (1226)	1475 (811)	1420 (674)	1698 (1331)
Fe (mg)	4.3 (2.2)	4.6 (3.0)	4.9 (2.5)	5.4 (2.9)*
Zn (mg)	3.28 (1.66)	3.76 (3.32)	3.99 (2.46) ^a	3.89 (2.53)

Significant differences (p<0.05): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE

One way RM ANOVA

* ST SE and TM ED approaching significance (p=0.056)

4.3.10 Correlations between test meal energy intakes (kcal) and daily energy intakes (kcal)

Table 4.7 displays associations between test meal energy intake (kcal) and daily energy intake (kcal). Daily energy intakes (kcal) were positively associated with energy intake (kcal) at the test meal (Figure 4.4). These correlations were strongest for the energy dense meals.

Table 4.7: Relationship between test meal energy intake and daily energy intakes

Meal	Pearson's correlation coefficient (r)	p value
ST SE	0.59	p= 0.001
ST ED	0.69	p= 0.001
TM SE	0.49	p= 0.004
TM ED	0.65	p= 0.001

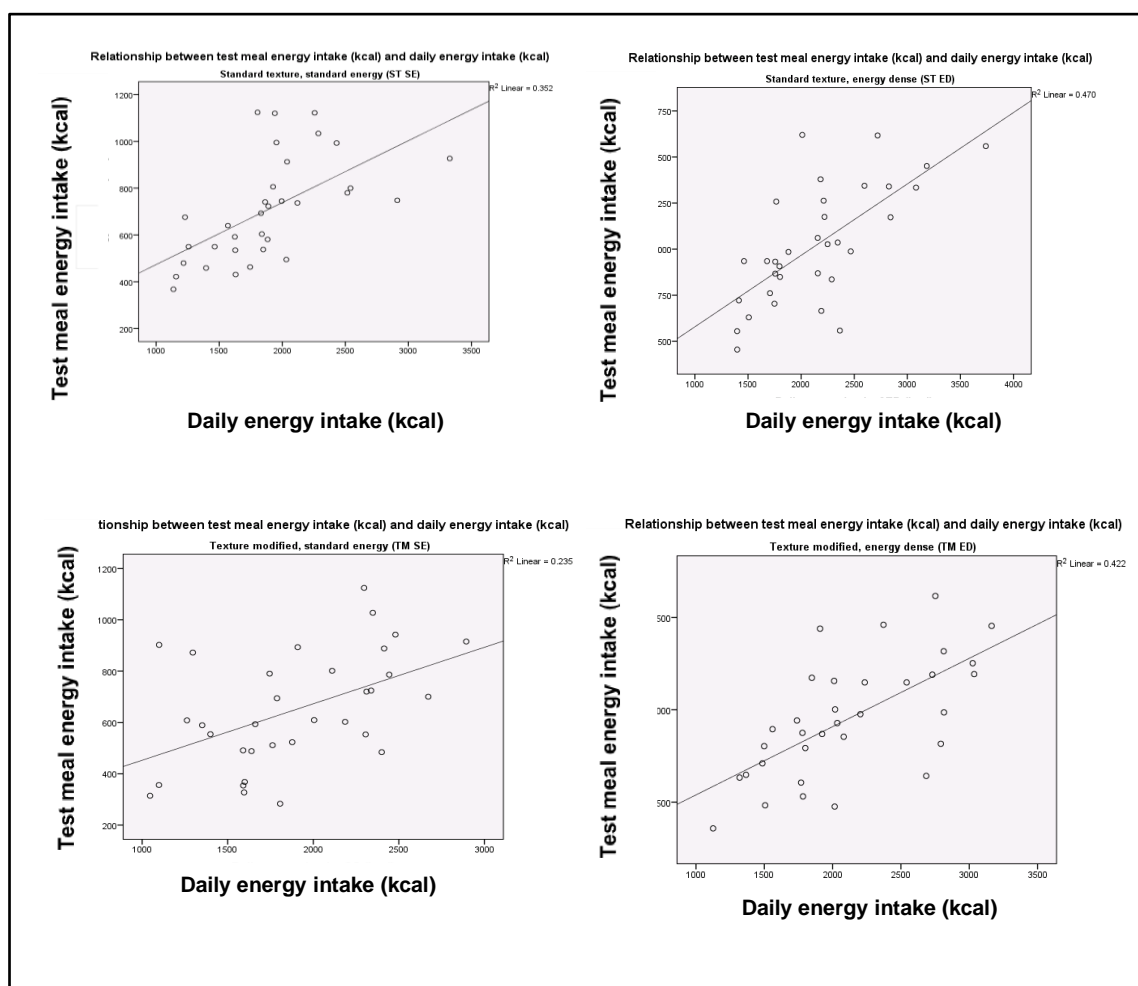


Figure 4.4 Relationships between test meal energy intakes and daily energy intakes (kcal)
(p and r values can be seen in Table 4.7)

4.3.11 Daily macronutrient intakes

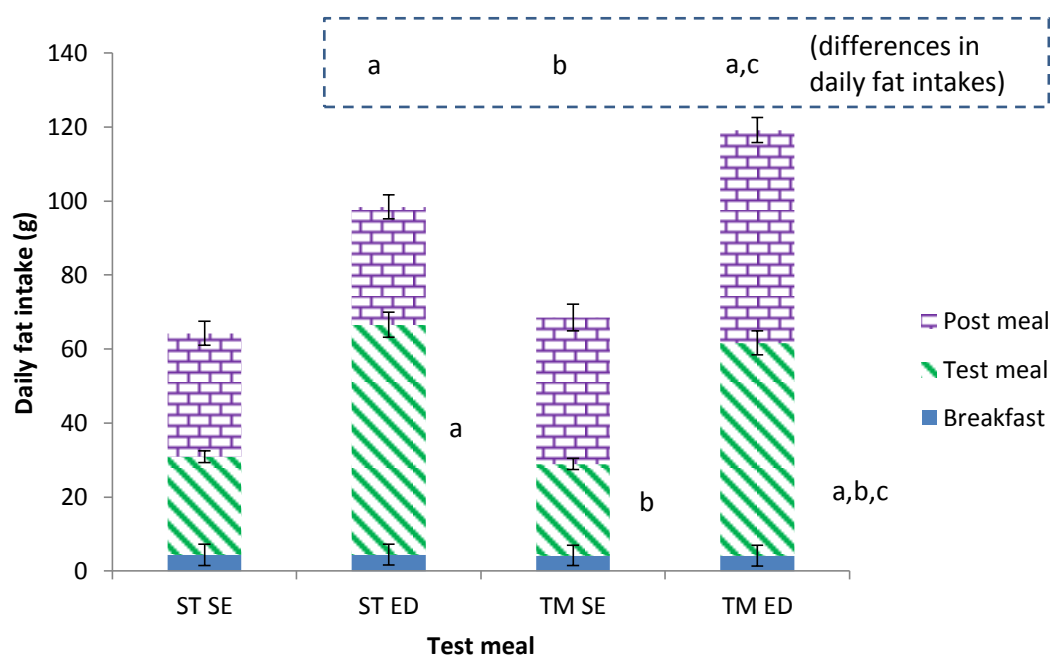
Daily intakes of both protein ($p=0.694$) and carbohydrate ($p=0.554$) did not significantly differ. Mean daily intakes of fat were significantly different across meals ($F_{(3, 30)} = 39.555$, $p<0.001$). Post hoc analysis identified that daily fat intakes were consistently higher on the days that enriched test meals were consumed ($p<0.001$). A breakdown of daily macronutrient intakes for each of the test meals can be seen in Table 4.8.

Table 4.8: Mean (SD) daily macronutrient intakes (n=33)

	Protein (g)	Carbohydrate (g)	Fat (g)
ST SE	91(39)	234 (64)	65 (24)
ST ED	85 (23)	241 (72)	99 (30) ^a
TM SE	87(22)	234 (71)	69 (22) ^b
TM ED	87 (29)	228 (67)	96 (26) ^{a,c}

Significant differences ($p<0.05$): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE
One way RM ANOVA

Daily and test meal fat intakes were found to be different across meals therefore a breakdown of the contribution of each meal occasion to daily fat intakes (g) is displayed in Figure 4.5.



($p < 0.05$ (at test meal and daily only): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE (RM ANOVA))

Figure 4.5: Mean (standard error) fat intakes (g) at the test meal and post-test meal across all test days (n=33)

4.3.12 Daily Micronutrient intakes:

Overall, there were no statistically significant differences for daily intakes of all micronutrients listed in Table 4.9. However, post hoc tests (unadjusted) revealed a difference in daily intakes of Na, with significantly greater ($p=0.04$) intakes on the ST ED day compared to the ST SE day.

Table 4.9: Mean (SD) daily micronutrient intakes

Nutrient	Daily intake ST SE	Daily intake ST ED	Daily Intake TM SE	Daily Intake TM ED
Vitamin A (ug)	3466 (1352)	3308 (1204)	3296 (1061)	3545 (1766)
B12 (ug)	6.4 (5.1)	5.6 (2.2)	5.3 (2.2)	10 (22)
Folate (ug)	359 (107)	352 (108)	332 (120)	352 (101)
Vitamin C (mg)	155 (108)	142 (96)	134 (94)	141 (96)
Vitamin D (ug)	1.9 (2.0)	1.7 (1.3)	1.9 (2.4)	3.1 (8.3)
Calcium (mg)	634 (224)	617 (252)	641 (236)	613 (240)
Na (mg)	2910 (1044)	3267 ^a (1109)	3036 (1140)	3143 (1057)
K (mg)	4307 (1540)	4237 (1212)	3995 (1211)	4246 (1665)
Fe (mg)	12.1 (4.2)	12.3 (4.6)	12.1 (4.2)	12.5 (4.0)
Zn (mg)	12.3 (3.6)	12.9 (5.2)	12.6 (3.9)	12.5 (3.8)

Significant differences ($p < 0.05$): ^a vs. ST SE, ^b vs. ST ED, ^c vs. TM SE
 One way RM ANOVA

4.4 Energy Compensation:

Using the formula outlined in chapter 3 (section 3.5.7), the percentage energy compensation between the meals of varying energy density have been calculated (Table 4.10)

Table 4.10: Percentage energy compensation observed with energy density

	Difference in post-meal energy intakes (kcal)	Difference in daily energy intakes (kcal)	differences in post- meal/differences in daily	% compensation
Energy Dense (ST)	48	315	0.15	15 %
Energy Dense (TM)	67	303	0.22	22 %

After consuming the test meal in the ST ED conditions, subjects only partially compensated for their increased energy intake (+ 315 kcal) (compared to ST SE) at the test meal by consuming 267 kcal (-48 kcal) after the test meal, resulting in a daily energy intake that remained higher on the ED test day (+ 260 kcal).

After consuming the test meal in the TM ED conditions, subjects only partially compensated for their increased energy intake (+303 kcal) (compared to TM SE) at the test meal by consuming 236 kcal (- 67) kcal after the test meal, resulting in a daily energy intake that remained higher on the ED test day (+ 225 kcal).

4.5 Appetite parameter results:

4.5.1 Baseline Appetite ratings (mm):

Mean baseline hunger ratings did not differ significantly between the different test days ($p = 0.521$). Mean (standard error) baseline ratings for fullness and desire to eat did not significantly differ between treatments ($p = 0.283$ and, $p = 0.469$ respectively).

4.5.2 Appetite ratings over time

The effect of consuming the test meal in all four conditions, on appetite parameters over time is shown in Figure 4.6 (a-c). There is a clear main effect for time for hunger ($p= 0.001$), fullness ($p=0.001$), and desire to eat ($p= 0.001$). Trends for ratings for hunger and desire to eat decreased over time with meal consumption, whilst trends for ratings of fullness increased over time with consumption of the test meal in all conditions.

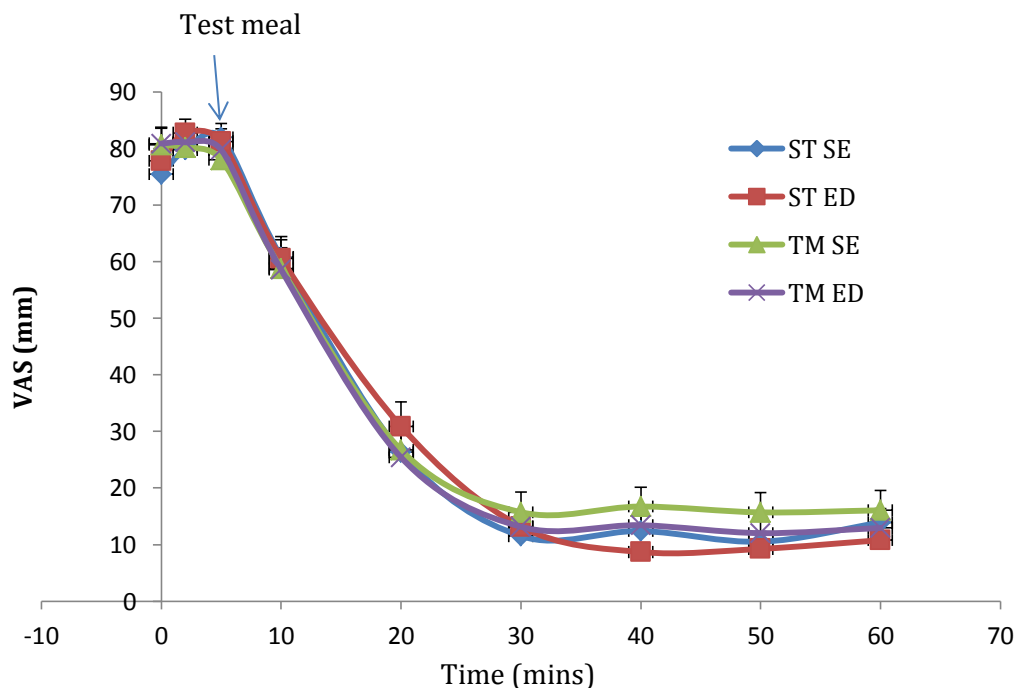


Figure 4.6 (a) Appetite-time profiles for hunger

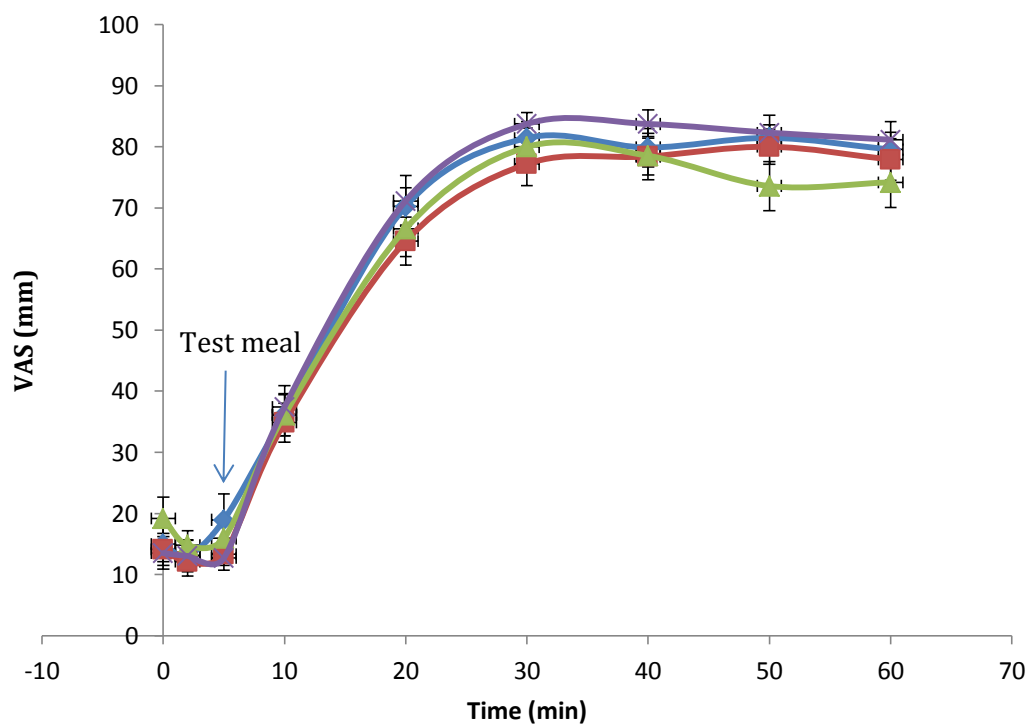


Figure 4.6 (b) Appetite-time profiles for fullness

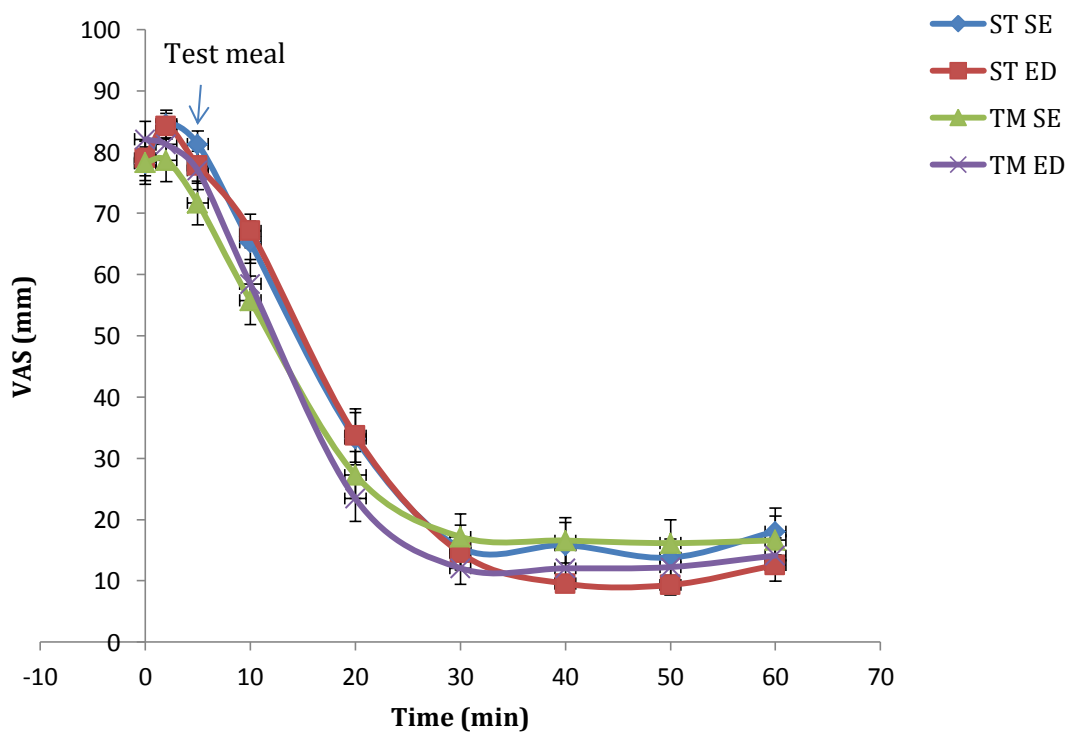


Figure 4.6 (c) Appetite-time profiles for desire to eat

Superficial examination of the appetite profiles (Figures 4.6 (a-c)) revealed that hunger was higher (but not significantly) for TM meals compared to ST meals at time points T7 (at 40 mins) to T9 (at 60 mins). Ratings for desire to eat tended to be higher for the ST meal compared to TM meals at time points T2 (at 3 mins) to T5 (at 20 mins), however post T6 (at 30 mins) the trend appeared to reflect a stronger desire to eat for the SE meals compared to the ED meals.

4.5.3 Between meal comparisons of subjective appetite responses

Between-group comparisons based on the RM ANOVA using AUC data examined the overall impact of alterations of meal form and energy density on mean appetite measures over the duration of the testing session. The AUC (Figure 4.7 (a-c)) for each meal did not differ significantly for hunger ($p=0.679$), fullness ($p=0.371$) or for desire to eat ($p=0.695$).

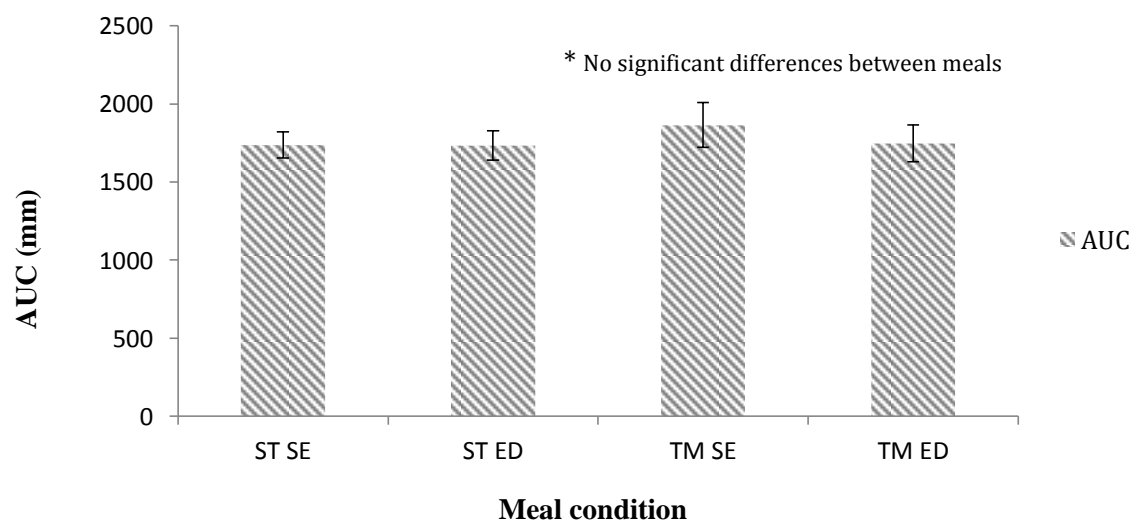


Figure 4.7(a) Mean (standard error) AUC hunger for each meal type (n=33)

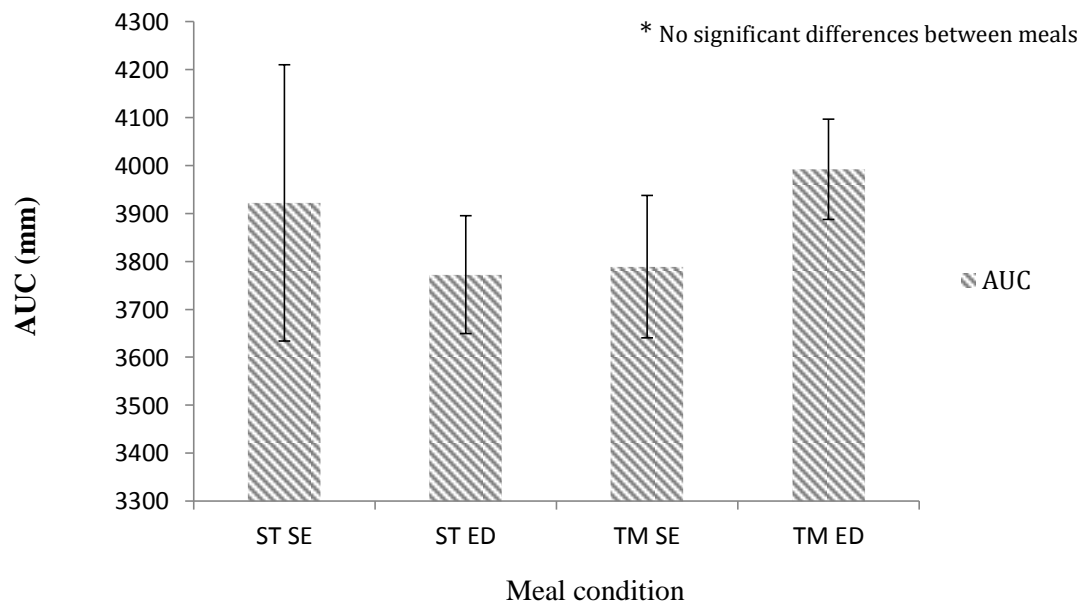


Figure 4.7(b) Mean (standard error) AUC for fullness for each meal type (n=33)

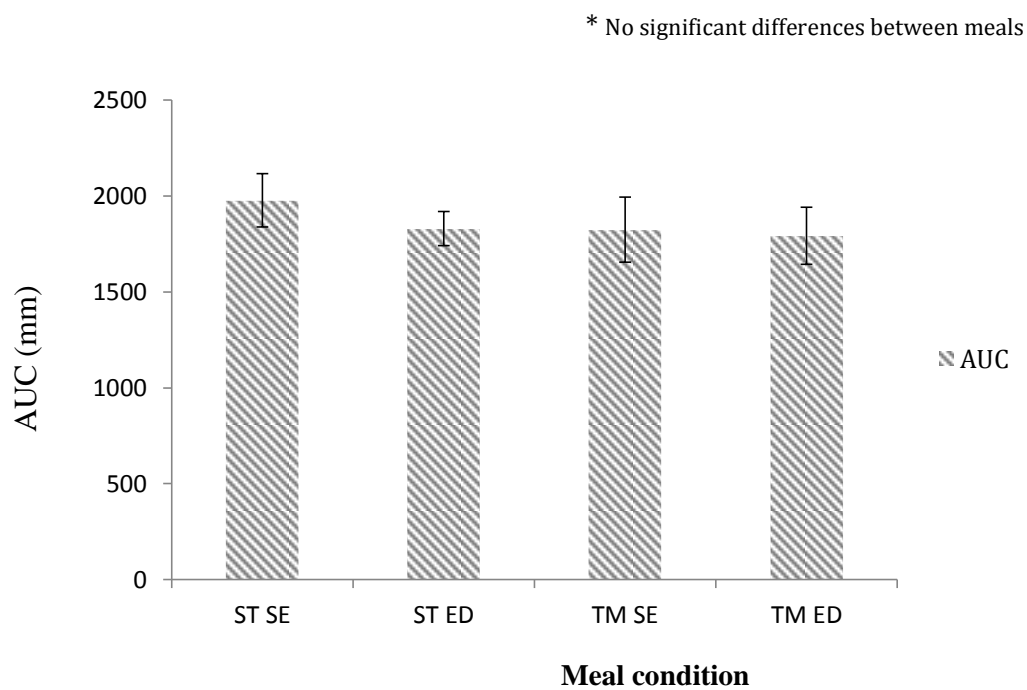
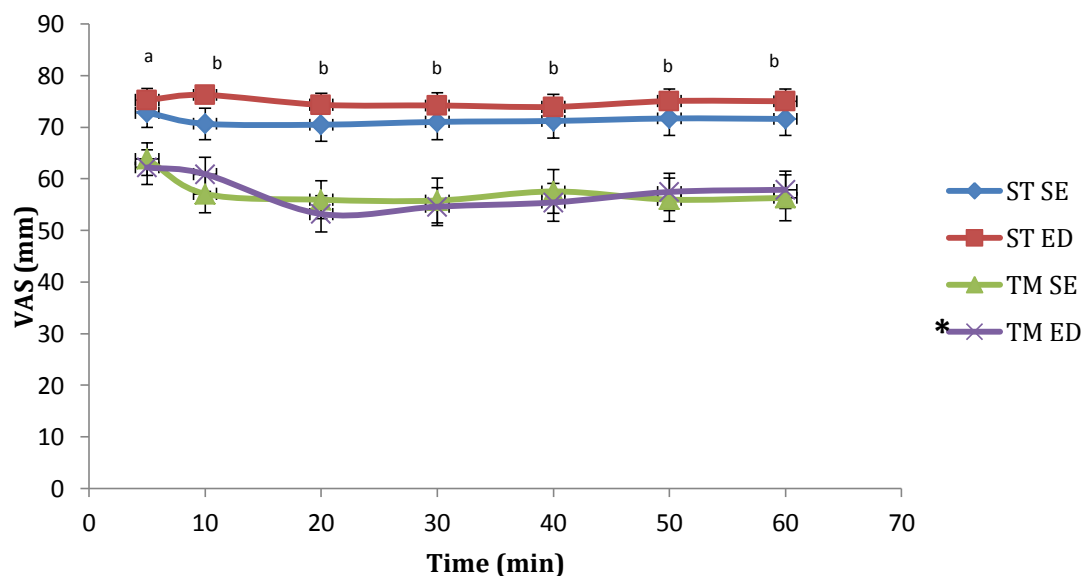


Figure 4.7(c) Mean (standard error) AUC for desire to eat for each meal type (n=33)

4.6 Palatability rating results

4.6.1 Meal acceptability ratings (mm):

Rated palatability at first taste (T3) (at 7 mins) was significantly different between the meal conditions ($p=0.005$) (Friedman's ANOVA) with the ST meals being rated as more palatable than the TM meals (Figure 4.8). Ratings for palatability declined slightly over time, however no significant differences were found between baseline and all other time points for all meals except for the TM ED meal ($p=0.001$).



Within * $p<0.05$: Friedman's ANOVA assessing changes in ratings for time (TM ED meal only)
Between: ^a $p=0.005$, ^b $p=0.001$ (Friedman's ANOVA)

Figure 4.8 Mean (standard error) appetite-time profiles for palatability (n=33)

AUC for palatability were significantly different between meals ($p=0.001$) (Figure 4.9). Although all meals were rated to be palatable (>50 mm VAS) post hoc analysis revealed that the ST meals were significantly more palatable than TM meals for both

SE ($p = 0.007$) and ED ($p = 0.001$) meal. Analyses of relationships between food intake (g) and appetite parameters (Table 4.11) showed that increased food intake was significantly associated with hunger (ST SE: $r = 0.55$, $p < 0.001$, ST ED: $r = 0.55$, $p < 0.001$, and TM ED: $r = 0.48$, $p < 0.004$) except for TM SE ($r = -0.126$, $p = 0.48$) which was rated as the least palatable meal over the testing session (AUC).

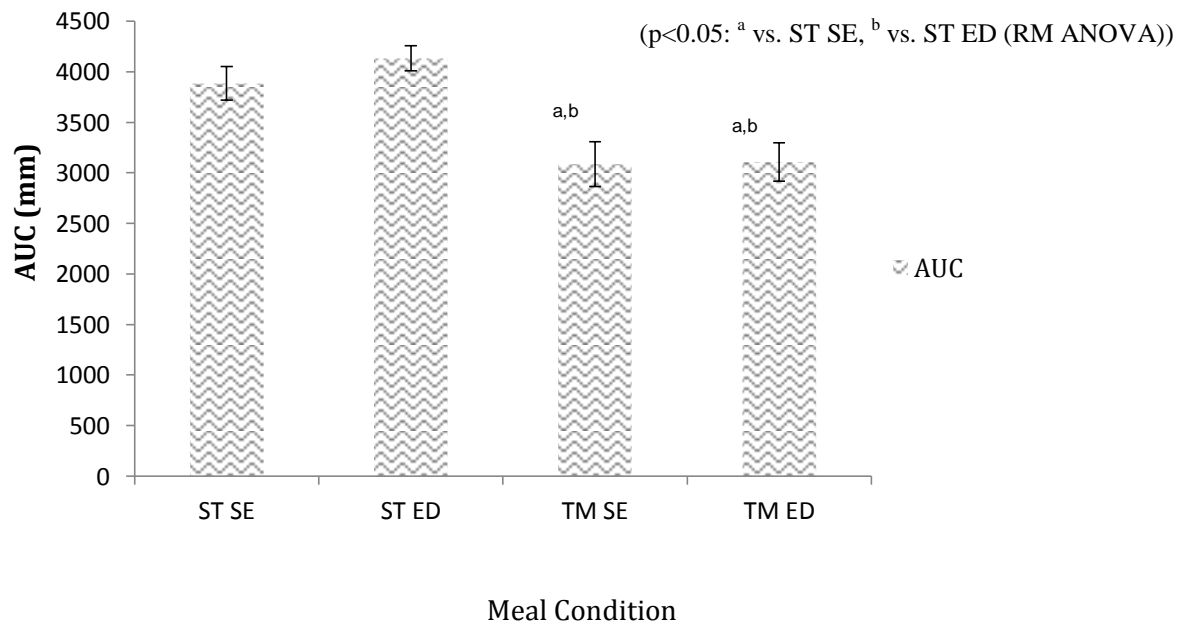


Figure 4.9 Mean (standard error) AUC for palatability for each meal type (n=33)

4.6.2 Associations between food intakes and appetite and palatability ratings

Pearson's correlation analysis indicated that food intake generally increased with palatability and desire to eat, although only reached statistical significance for the TM SE meal (Table 4.11). Food intakes tended to decrease with increasing fullness, this finding being strongest for the TM ED and not statistically significant for all

other meal conditions. Food intake increased significantly with increasing hunger for all meals other than the TM SE which actually demonstrated that intakes decreased with hunger, although not significantly. All correlations for food intakes and appetite/palatability responses can be seen in Table 4.11.

Table 4.11 Correlation coefficients for appetite ratings and food intake (g)

Meal	Food intake and Palatability	Food intake and Hunger	Food intake and Fullness	Food intake and Desire to eat
ST SE	r = 0.251	r = 0.546*	r = - 0.312	r = 0.178
ST ED	r = 0.106,	r = 0.553*	r = - 0.285	r = 0.564*
TM SE	r = 0.371*	r = - 0.126	r = - 0.013	r = 0.170
TM ED	r = 0.279	r = 0.484*	r = - 0.550*	r = 0.230

* p<0.05 (Pearson Product moment correlation analysis)

4.7 Time until satiation, and periods of satiety

4.7.1 Time (mins) taken to consume meal until satiation

It took subjects slightly longer to consume ST meals compared to TM meals (Mean +/- SD (ST SE: 19 +/- 6 mins (95% C.I 17-21 mins), ST ED: 20 +/- 7 mins (95% C.I 17-22 mins), TM SE: 17 +/- 7 mins (95% C.I 15-20 mins), TM ED: 18 +/- 6 mins (95% C.I 17-20 mins))). However the time (mins) taken to consume each test meal was not significantly different ($F_{(3, 96)} = 2.45$, $p = 0.068$).

4.7.2 Period of satiety

Two subjects failed to consume > 100 kcal on one post-test meal occasion (one subject consumed < 100 kcal at subsequent occasions (ST ED meal day), and one subject reported to be too busy to eat after the testing session (TM SE meal day)) therefore their data was excluded from the analysis for this outcome (n=31). The period of satiety (Figure 4.10) was not significantly different between meals ($F_{(3,90)}=1.68$, $p=0.177$) although there tended to be longer time (min) interval between point of satiation and next the eating occasion for the ED meals compared to the SE meals, particularly for the TM meals (Mean +/- SD) (ST SE: 226 +/- 113 mins (95% C.I 185-267 mins), ST ED: 238 +/- 126 mins (95% C.I 192-285 mins), TM SE: 192 +/- 116 mins (95% C.I 149-234 mins), TM ED: 245 +/- 116 mins (95% C.I 203-288 mins)).

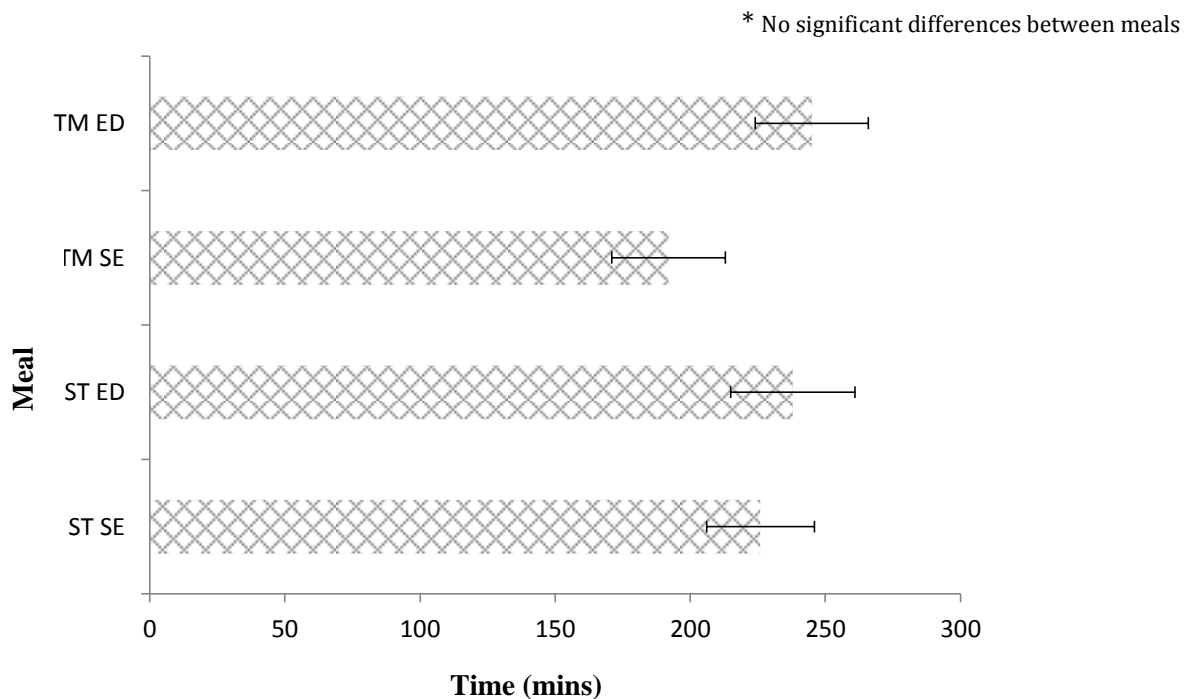


Figure 4.10: Mean (standard error) time (mins) until next eating occasion (> 100 kcal) for each meal condition (n=31).

Chapter 5: Discussion

5.1: Discussion

This experimental study investigated the impact of altering food form and energy density on food intakes (satiation and satiety), appetite responses and palatability ratings. All food alterations adopted in the current study were made in line with guidance in place for food provision in the clinical setting. These included altering energy density to replicate minimum energy provision for those described as both “nutritionally well” and “nutritionally vulnerable” (Scottish Government 2008) and altering the texture to meet requirements to be served within a TMD (namely that of “Texture C” (BDA 2012a).

Thus this study aimed to evaluate these physical alterations to food, whilst gaining insight into their potential as a strategy for encouraging intakes in those who may otherwise struggle to consume adequate energy intakes. This study therefore had a unique application since previous studies investigating these physical food alterations (texture and energy density) on eating behaviour focused on the prevention of weight gain as part of weight management strategies (Rolls et al. 2004; Mazlan et al. 2006; Ello-Martin et al. 2007; Lowe et al. 2008; Mattes and Campbell 2009).

It was hypothesised that altering a meal’s texture to represent one suitable for provision as part of a texture modified diet (TMD) would result in reduced food (g) and energy (kcal) intakes as has been demonstrated previously in clinical studies (Johnson et al. 1995; Nowson; 2003; Wright et al. 2005; Bannerman and McDermott 2009). Further, it was hypothesised that subsequent enrichment of this TMD meal

could result in increased energy intakes at a single eating occasion. It was unknown whether individuals would compensate by reducing energy intakes or by altering their macronutrient intake at eating occasions later in the day and thus, whether this strategy of energy enrichment at a single eating occasion has the potential to improve total daily energy intakes is unclear.

Findings from this research support the use of energy enrichment as a strategy for increasing short term energy intakes. This approach demonstrated similar improvements in both test meal and daily energy intakes (kcal) regardless of the texture of the meals. As hypothesised, modifying the texture of the test meal in line with current guidelines (BDA 2012a) significantly reduced both food (g) and energy intakes (kcal) at a lunch time test meal occasion. However by enriching the test meals (in both ST and TM forms), energy intakes (kcal) increased significantly at the test meal eating occasion and remained higher over the test day compared to when the standard energy (ST SE and TM SE) test meals were consumed.

Increased energy intakes appeared to be related to the increased fat content of the enriched meals, as intakes (at the test meal) of all other macronutrients between the test days remained the same. Despite differences in food and energy intakes across the meal conditions, no differences in appetite responses (hunger, fullness or desire to eat) were observed. Ratings for palatability were however reduced significantly with texture modification. There was no evidence of energy compensation for energy consumed after the test meal as both energy and macronutrient intakes consumed post-test meal did not differ between the test days regardless of the energy and macronutrient composition of the test meal. Extended detail of the key findings of this research including how they may have relevance for application in the clinical

setting is discussed subsequently (section 5.2). Firstly an appraisal of the test meal alterations and their impact on meal composition and rated palatability ensues.

Four meals differing in texture (form) (standard, or modified (“Texture C” (BDA 2012a), and/or energy density (1.0 kcal/g or 1.4 kcal/g)) were successfully developed (chapter 2, section 2.2). This allowed direct comparisons to be made to evaluate the impact of both texture modification and/or energy enrichment on the outcome measures (chapter 3, section 3.5), as each meal developed with the altered variable in question (texture and energy density) had a matched control (chapter 2, Figure 2.2).

The nutritional content (both macronutrient and micronutrient) of the test meal was unaltered by modifying the texture, to create a texture modified version of the meal (ST SE → TM SE). However maintaining a constant nutritional profile of the test meals during texture modification was central to the current study design, and therefore this was ensured during the development of the meal (chapter 2, section 2.2). This was necessary as it allowed for the direct comparison of the effect of texture (form) on the outcome measures whilst holding the energy and macronutrient content constant as altering these may have introduced confounding variables (chapter 2, section 2.1.2, Table 2.1). The same precision for ensuring equal nutritional profiles between standard meals and their modified counterparts may however not reflect what occurs in practice during the production of TMD meals. This has been demonstrated by Vigano et al. (2011) who reported reduced nutritional quality with additional degrees of modification. For example, it was reported that

compared to normal diets; pureed and liquid diets presented higher moisture content as well as reduced energy, protein and lipid content (chapter 1, section 1.1.2).

It is stated in national guidelines that therapeutic diets must be capable of meeting the dietary requirements for the patients using them (Scottish Government 2008). When considering food provision in hospitals; to ensure dietary needs are met it is important that standard recipes are developed and followed ensuring adequate provisions are met. As TMD meals may be nutritionally dilute, this thereby puts an individual receiving this therapeutic meal at a nutritional disadvantage even before the meal is consumed. It is in fact this risk of nutritional dilution (in particular reduced energy density) during the usual preparation of texture modified meals that strengthens the argument for the energy enrichment of these meals.

In the current study, alteration of energy density (SE (1.0 kcal/g) → ED (1.4 kcal/g)) of the meals (ST and TM) was mainly achieved through the addition of fat based ingredients; butter and cream (chapter 2). Enrichment with store cupboard items successfully enhanced the energy content of the meal such that the requirements for the provision of an energy dense meal (*i.e.* for “nutritionally vulnerable”) as stated in *Food in Hospitals* (Scottish Government 2008) were met. In fact, the energy dense meals contained 537 kcal per portion (390 g) representing a 152 kcal (*i.e.* 40%) increase in energy content whilst maintaining a constant protein content across meals (24 g per portion). This level of enrichment was consistent for both the standard texture (ST ED) and texture modified (TM ED) meals.

Although currently no guidance exists which suggests recommendations for levels of enrichment; the current study demonstrated the capability of enriching by 40%

without negatively impacting on absolute food intakes (g) over one day. Others have enriched meals by levels of 50% also successfully demonstrating improvements in daily energy intakes (Odlund Olin et al. 1996). It was however important to consider if these levels of enrichment may have clinical benefit, for those with reductions in energy intake through prescription of a TMD.

In the study by Wright et al. (2005) it was demonstrated that those receiving a texture modified diet consumed 535 kcal less in daily energy intakes compared to a group receiving a standard diet. If the meals in the study by Wright et al. (2005) had been enriched by 40%-50% and the same volume was consumed, patients may have been able to partially make up for the lower food intakes (g) (and thus energy intakes (kcal)) observed with consumption of the texture modified meals. The effect of enriching meals to different levels (40%, 50% and 60%) on energy intakes (kcal), assuming the same quantity (g) of food is consumed can be seen in Table 5.1.

Table 5.1: The effect of enriching meals to varying levels on potential energy intakes

	Daily intake (kcal)	(+ 40%) Enrichment of TMD	(+ 50%) Enrichment of TMD	(+ 60 %) Enrichment of TMD
Control group	1463 kcal*	1463 kcal	1463 kcal	1463 kcal
Texture modified group	928 kcal*	1300 kcal	1392 kcal	1484 kcal
Difference in intakes	-535 kcal*	-163 kcal	-71 kcal	+21

* Data from Wright et al. (2005).

Using data from a study comparing intakes between standard texture meals and texture modified meals (Wright et al. 2005) it appears that by enriching the meals by 60% (Table 5.1), patients could have fully compensated for the reduced energy intakes as a result of reduced food intakes with TMD meals, once enrichment to this level did not further impact on food intakes at the meal. It should be considered that the current study evaluated enrichment of one meal component (*i.e.* main meal at lunch time) on daily energy intakes. It is yet to be evaluated if enrichment across all meals supplied would result in similar increases in intakes, and also if this would impact on subsequent intakes.

It is also possible that enrichment through the addition of fat may further promote within-meal food intakes due to the high palatability of this macronutrient (Blundell and MacDiarmid 1997; French and Cecil 2001) as well as evidence supporting fat driven hyperphagia (Taha 2010). Although in the current study this was not demonstrated as no significant differences were observed in absolute food intakes (g) with energy enrichment (chapter 4, Table 4.2), therefore this too would need to be evaluated further.

In the current study, as a result of altering the energy density of the meals, the macronutrient composition of the test meals differed as the energy dense meals contained significantly more total fat (g) and energy from fat (as expressed as a percentage of total meal energy) than the standard energy meals (ST SE and TM SE). The percentage of total meal energy contributed from the macronutrients differed between the standard and energy dense meals as it is impossible to alter the energy density of a meal whilst maintaining macronutrient content without also altering another characteristic of the meal such as volume.

In fact, volume (chapter 2, section 1.1.2) may initially impact on satiation to a greater extent than that of macronutrient composition. Rolls et al. (2000) demonstrated that subjects (males) consumed 12% less from a test meal (96 kcal/ 402 kJ, $p=0.04$) after the consumption of a 600 ml preload (milkshake with air added) compared to a 300 ml (milkshake) preload, matched for weight and macronutrient content. Volume of food can influence cognitive perception of the food, with greater volumes believed to be more satiating (Brunstrom et al. 2010). Furthermore, volume has been shown to impact on SSS (as rated by a decrease in pleasantness) greater than energy content, potentially contributing to early satiation (Bell et al. 2003).

It is also plausible that volume will impact on gastric distension, with greater volumes leading to greater feelings of fullness (Geliebter et al. 1988; Marcini et al. 2001). Considering the sequence during which food is consumed, digested and absorbed (chapter 1, section 1.5); the volume of the ingested food will stimulate the stretch receptors in the stomach wall (Phillips and Powley 1996) which will initially dominate the satiety response. Subsequently, the activation of nutrient and osmotic receptors in the intestine via stimulation from post absorptive metabolic feedback occurs (Himaya and Louis Sylvester 1998) after the initial gastric distension (Benelem 2009).

The difference in fat content should therefore be particularly considered when interpreting the data regarding food consumption at later meal occasions (*i.e.* post-test meal). However, as fat is said to have a weak satiety effect (Rolls et al. 1988; Westerterp-Plantenga 2004) it is argued that this difference in total fat content between the meals of varying energy density will in fact have little effect on satiety and subsequent intakes. It was considered a strength of the current study that the

quantity of carbohydrate (g) and protein (g) was maintained across the meals. Fibre content was also maintained (4.2 g NSP (SE) and 4.1 g NSP (ED)) across the meals which was particularly important due to the documented effects of fibre on satiety as reviewed earlier (chapter 2, section 1.1.2).

Micronutrient content was largely maintained across the test meals also (chapter 2, Table 2.6), however some (vitamin A, calcium and sodium) differed slightly with enrichment. The enriched meals contained less vitamin A (50 ug (7 % RNI)), less calcium (18 mg (3 % RNI)) and more sodium (50 mg (2 % RNI)). These differences were considered to be small (relative to % of daily recommendations) and therefore likely had a negligible impact on satiety.

There is a paucity of literature suggesting that calcium is implicated in the development of satiety (Davies et al. 2000; Zemel et al. 2000). One study investigating calcium supplementation (500 mg Ca) demonstrated significant reductions (116 kcal) in subsequent intakes (Al-Mana et al. 2012). However it is unlikely that differences of 18 mg as observed in the current study would be sufficient to induce a substantial effect. On closer inspection of compositional breakdown of the test meals, it appeared that the enriched meal contained less calcium due to the replacement of semi-skimmed milk with double cream. Whereas differences in vitamin A and sodium contents between the meals were most likely attributed to the different composition of the spreads used.

Whilst meal composition determines the provision of nutrients, it does not solely determine the consumption of nutrients. Palatability, for example is well documented to be a driver of food intake (Blundell and Stubbs 1999; Stubbs and Whybrow 2004).

In fact, palatability of food has been shown to even override physiological feelings of appetite (Lowe and Butryn 2007). TMDs are often reported to be aesthetically inferior and less palatable than unmodified texture meals (SIGN 119 2010), which potentially contributes to reduced consumption of these meals rendering them not ‘fit for purpose’ (*i.e.* to maintain safe and sufficient oral nutrient intakes). In the current study, it was observed that the texture modified meals were rated to be significantly less palatable than the standard texture meals. It is noteworthy however that these texture modified meals were still deemed to be palatable as rated during the testing session (chapter 4, section 4.6, Figure 4.8).

Their acceptable palatability, (although less than the unmodified meals) was further demonstrated by the rate of their consumption (measured in grams (chapter 4, Table 4.2)), which was similar (albeit less) to the unmodified meals. It was not possible in the current design to maintain the palatability with texture modification whilst ensuring the composition was matched. Further development of these therapeutic meals, outside the constraints of the current study design is warranted to ensure the production of aesthetically acceptable meals. This in itself can improve intakes of these meals (Cassens et al. 1996) and therefore may contribute to overall improvements in intakes in those prescribed a TMD.

It is likely that the reduced palatability of the texture modified meals contributed to the reduction of intakes in the current study. Although when examined further, analysis (Pearson correlation coefficient) did not reveal a clear significant correlation for palatability and food intake, except for the TM SE meal. This meal was in fact rated to be the least palatable meal (as determined by the AUC) (chapter 4, section

4.6, Figure 4.8) and resulted in the lowest absolute intakes (g) at the testing session (Chapter 4, Table 4.2).

Whilst these findings suggest that palatability may be contributing to the reduced intakes (*i.e.* as shown with the TM SE meal) it is unlikely that this was the sole factor for the reduced intakes of these meals. This is thought to be the case as a clear trend with reduced palatability and resulting intakes was not observed across all meals. The impact of palatability for driving food intakes itself is complex. It is thought that food that is highly palatable activates the reward system, thereby affecting ingestive behaviour. The driving force of this “reward eating” is thought to be enjoyment rather than energy deficit (Pelchat 2002). This suggests therefore that highly palatable food overrides the body’s well established appetite regulatory systems (Rolls 2007), resulting in over consumption.

It is however not clear if consumption of food which is deemed to be less palatable demonstrates similar but inverse, trend on intakes. Stubbs and Whybrow (2004) reviewed this and reported findings from a study by De Castro (1987) which investigated the relationship between rated palatability and intakes (using self-recorded food intakes methods). Here it was noted that, there appears to be a threshold where food will be deemed acceptably palatable to be ingested (Stubbs and Whybrow 2004). Essentially, if food is deemed unpalatable, it will be avoided and therefore an accurate relationship between intakes of less palatable foods cannot be produced. Unfortunately, for those prescribed a texture modified diet the option not to ingest these foods does not exist without negatively impacting on nutritional status, as these individuals cannot safely consume foods of different textures which may be deemed more palatable.

It is not clear exactly why the standard texture meals were rated to be more palatable; however it is possible that it may be due to the altered mouthfeel of the TM meals due to the disrupted food structures as a result of blending, which may alter the texture and flavour of the meal (Schiffman and Warwick 1993). Also, texture plays an important role in food identification (Murphy 1985). Therefore reduced intakes may be partially attributed to the fact that the texture modified meals did not represent what is anticipated or what one would typically consume. These findings further confirm the importance of developing meals (including TMD meals) that are palatable and well presented in order to facilitate consumption of these meals to ensure requirements are met.

It should be reiterated here that the alterations made to the test meals were disguised as much as possible during the testing session (discussed in chapter 2, section 2.2). This was achieved by serving all meals in an identical dish, and all meals being topped with a layer of mashed potato of the same consistency. Once the meal had been served on the plate however the texture alteration was detectable although no significant differences in appetite ratings (hunger, fullness, desire to eat) were observed from baseline (T1, at 0 mins) (*i.e.* when the alteration was not detectable) and when the meals were served (T2, at 3 mins) (*i.e.* when the alteration was likely detected) between the meals. It is noteworthy that despite the alterations of the meals, the rated desire to eat was not different between the meals. This suggests that cognitive belief about the meal, known to impact on eating behaviours (Blundell et al. 1999, (chapter 1, Figure 1.2); Brunstrom et al. 2011) was unlikely to have been affected.

Aside from increasing the energy density of meal, enrichment may further improve intakes of TMD meals, as energy density positively correlates with food intakes (Stubbs and Whybrow 2004). In the current study it may have been assumed that the palatability of the energy dense meals would have been greater than the standard energy meals as fat is known to be palatable (Blundell and MacDiarmid 1997; French and Cecil 2001). It was however central to the study design that the palatability between the meals (varying in energy density) was matched in order to control for the confounding effect of palatability on intakes.

In the current study, palatability was not rated to be significantly different with the increased energy density. It is possible that it is due to the lack of observed difference in palatability ratings between the meals differing by energy density which resulted in similar absolute intakes (g) at the testing sessions. Outside of the experimental setting and the restrictions of the current study, fat based ingredients could be added to further promote energy intakes by improving the palatability of the meals. After all, it is reported that high fat foods generally promote food and energy intakes (Blundell and MacDiarmid 1997; Warwick et al. 2003; Erlanson- Albertsson, 2005; Taha 2010).

Although fat is palatable, there may be a threshold for which foods can be enriched before they actually become unacceptable and this may vary depending on the foods that are being enriched, and on individual taste thresholds. It has been demonstrated that aesthetic ratings decreased with higher levels of enrichment. In one study (Memmott et al. 2010); eleven females (19–45 years) rated four levels of enrichment for different foods (namely soup, milk pudding and, mashed potato). Enrichment was achieved through the addition of store cupboard items such as milk powder and

cream. Higher levels of enrichment were found to have a detrimental effect on the aesthetic ratings of soup (texture $p=0.038$) and milk-pudding (taste $p=0.034$; texture, $p=0.006$; pleasantness, $p=0.021$; aftertaste, $p=0.015$).

Currently, there is no specific advice in the guidelines surrounding the levels to which meals should be enriched, in order to improve energy intakes without negatively impacting on the aesthetics of the meal. If foods are enriched to an unacceptable level, they may be rejected and therefore will have no nutritional benefit. To establish these thresholds for fat detection, more work is needed across a variety of foods. Hoppert et al. (2012) did however demonstrate that it is difficult for subjects to distinguish between custard-type food emulsions on the basis of the fat content (of 5, 15 or 25 g/100 g) once the products' texture, sweetness and flavour is kept constant. Further the current study demonstrated enrichment up to 40% does not impact on the palatability or cognitive belief (desire to eat) of the food.

Thus far the impact of texture and energy density alterations on meal composition and palatability, both of which influence nutrient intakes, have been discussed. However to fully appreciate the potential of these meals (*i.e.* enriched TMD meal) for facilitating food and energy intakes, consideration of their influence on appetite and eating behaviour needed to be addressed. Although in the current study modifying the texture did not impact on the nutritional content of the meals (in both SE and ED conditions), texture modification was found to negatively impact on intakes (g) consumed at the session. These observed differences in intakes demonstrate that the texture modified meals ("thick puree", (BDA 2012a)) were

more satiating than the meals in the standard texture form (fork mashable, (BDA 2012a)). This was proven by the fact that subjects consistently consumed less (g) (in both SE (9 %, 66 g) and ED (7 %, 51 g) forms) of these meals to reach the point where they felt comfortably full.

As previously demonstrated in experimental studies (chapter 1 section 1.6.2), this shows that indeed the form in which a food is consumed can affect food intakes, and consequently energy intakes. In fact, this observed reduction in food intake with texture modification of 66 g (SE) and 51 g (ED) had a significant negative impact on energy intake consumed at the test meal, reducing energy intakes by 59 kcal (SE) and 71 kcal (ED). Although this reduction in energy intake resulting from texture modification may appear small (representing <10% of a reduction in energy intakes) this was statistically significant ($p < 0.05$). If similar reductions in energy intakes were also observed at other meals this has the potential to become clinically significant, leading to weight loss over time.

The fact that intakes were reduced with the TM meal is in line (although less pronounced) with reductions in intakes that are often observed in those who are receiving a TMD for the nutritional management of a range of medical conditions, including dysphagia (Nowson et al. 2003; Wright et al. 2005; Bannerman and McDermott 2011) (chapter 1, section 1.1.2). It is difficult to compare these particular findings with the current study directly however as these studies, conducted in clinical settings tend to compare intakes from different groups of patients (*i.e.* using unpaired designs), in uncontrolled settings (*i.e.* a hospital ward or in a residential care home) (Wright et al. 2005; Bannerman and McDermott, 2011). Nonetheless it is interesting that the trend of reduced intakes (although less pronounced) of texture

modified meals was also observed in the current study in a healthy sample with unrestrained eating behaviour.

The results of the current study may support what is often observed in clinical settings with the provision of TMD resulting in reduced intakes (Wright et al 2005). However this same trend is not always demonstrated in other controlled experimental studies using healthy subjects. Again, due to the differences in the foods studied it is difficult to directly compare the current study with those conducted in other healthy subjects in experimental settings (Mattes 2005; Flood-Obbagy and Rolls 2009). For example, a number of the studies conducted in healthy individuals have investigated differences between liquids and semi-solids (Mattes and Rothacker 2001; de Wijk et al. 2008; Zijlstra et al. 2009) (chapter, 1, section 1.6.2) whereas the current study investigated semi-solids compared to solids. Thus the extremes in the differences in textures studied vary largely which likely further affects intakes (chapter 1, section 1.6.2).

Furthermore the types of foods studied differed greatly. In other experimental studies individual items such as fruit, vegetables, and milkshakes of a range of textures were investigated whereas the current study evaluated a complete meal; cottage pie that was developed to specifically match guidelines for TMD. It has already been discussed how the physical properties of foods can influence eating behaviour (chapter 2, section 2.1.2, Table 2.1). Aside from texture and energy density, other properties which can influence eating behaviour include; volume and portion size (Rolls et al. 2000; Phillips and Powley 2000; Brunstrom et al. 2010) macronutrient composition (Stubbs and Elia, 2001; Ryan et al. 2003; Benelem 2009) fibre content

(Kristensen and Georg Jensen 2011) and palatability (Blundell and Stubbs 1999; de Graaf et al. 1999).

Thus due to the various foods studied (*i.e.* fruit, vegetables, milkshakes, candy) it is likely that these presented differing physical properties which likely contributed to the differences in the findings between the current study and other previously discussed experimental studies (chapter 1, section 1.6.2). As discussed earlier in this chapter it is also possible that in the current study, the reduced palatability of the TM meals added to the reduced intakes. In other experimental studies which demonstrate the satiating effects of more viscous products, meals were matched for palatability (Mattes and Rothacker 2001; de Wijk et al. 2008; Zijlstra et al. 2009) (chapter 1, section 1.6.2).

It should also be considered that in the current study despite the fact that subjects were asked to refrain from consuming alcohol containing beverages it was noted during analysis of the diet diaries that not all subjects complied to the request completely. It appeared that seven subjects (21 % of sample (n=33)) reported to consume some alcohol on at least one of the test days. As the volume reported to be consumed was so small (*i.e.* one glass of wine) and of low alcohol content (~11 % ABV) it was thought that the effect on appetite would be minimal. Therefore it is unlikely that this alone contributed to the differences observed in the current study and other experimental studies. Particularly as in a previous study by Poppitt et al. (1996), alcohol (30.6 g) was found to have no significant effect on subsequent energy intake. The energy consumed from the alcoholic beverage was however included in the daily energy intake calculations. It could be argued that this does demonstrate the level of accuracy in the dietary recording by subjects due to the fact that alcohol

consumption was disclosed despite the fact that they were requested to refrain from consuming it.

Along with the current study, what is observed in practice (Wright et al. 2005; Bannerman and McDermott 2009) and the results from experimental studies previously discussed (Rolls et al. 1990; Marcini et al 2001; Flood and Rolls 2007; Flood-Obbagy and Rolls 2009; Zijlstra et al. 2008; 2010; Mattes and Campbell 2009), the influence of texture on eating behaviour continues to be demonstrated. However the mechanisms behind it remain unclear and thus it is difficult to establish a directional hypothesis. Further the impact of texture on other qualities of the food (such as palatability, cognitive perception, and the behaviour of foods in the oral and gastric phases) makes it difficult to isolate the impact of texture on intakes alone.

In one study by Zijlstra et al. (2010) hard-solid foods were reported to be more satiating than soft-solid foods (food studied were; luncheon meat (hard and soft), meat replacer (hard and soft), candy (hard and soft) (chapter 1, section 1.6.2)). It is unclear why exactly this reduction in food intake (*i.e.* earlier satiation) with altered form occurred. Zijlstra et al. (2010) proposed that the texture of a meal impacts on satiation perhaps due to the differences in oral exposure time, which is likely to play a role in determining food intakes within a meal (*i.e.* induce satiation).

With respect to the current study the ST meal (Texture E) represented a solid texture (as it required chewing) although arguably it was a soft-solid, whilst the TM meal (Texture C) represented a semi-solid or puree texture. As solids require chewing before deglutition, which semi-solids often do not, for those without mastication or swallowing difficulties; solids may actually spend more time in the oral cavity which

subsequently impacts on appetite and eating behaviour. It has been demonstrated that the mechanism of chewing pastilles reduced subsequent intake at a test meal (pasta, tomato sauce, bread and butter) by 13 % (-117 kcal) and 11 % (-92 kcal) compared to consumption of a preload of a sweet drink or preload of water respectively (Lavin et al. 2002).

Hetherington and Boyland (2007) found that simply chewing gum resulted in reduced hunger and increased fullness ratings compared to when no gum was chewed, demonstrating the potential impact of chewing on suppressing appetite. In the same study, researchers demonstrated that by chewing gum prior to consumption of a test meal, energy intake at the test meal was significantly decreased, although only by 36 kcal ($p=0.04$). Whilst this does not seem like a substantial decrease in energy intake, it does further demonstrate how the action of chewing can reduce intakes even without evoking post-ingestive feedback involved in the regulation of appetite (chapter 1, section 1.5).

Perhaps similar reductions would be observed as a result of increased oral exposure time in those with mastication difficulties. In which case, these small reductions in energy consumption would be encountered at each meal occasion, which could impact on intakes and weight status over time. The current study demonstrated that the foods that would typically require less chewing (*i.e.* 'Texture C' vs. 'Texture E') were more satiating. Perhaps therefore it is as suggested by Zijlstra et al. (2011), oral exposure time which is involved in the development of satiation. Oral exposure time was however not specifically measured in the current study as this would have disturbed the subjects and distracted them from their true feelings of appetite, thereby

confounding data regarding food intakes. This theory therefore cannot be confirmed, however warrants further study.

Sensory cues about a food can activate the cephalic responses of digestion which are triggered by sensory contact with foodstuffs, rather than by the post-ingestional consequences of food (Powley 1977). Whilst these sensory cues include both smell and sight, it has been shown that the oral exposure to food enhances the effects of gastric and intestinal exposure to food, on appetite and subsequent food intake (Smeets and Westerterp-Plantenga 2006). This is why those receiving enteral or parenteral nutrition frequently report that despite the provision of nutrients, their appetite is unaltered such that feelings of hunger persist (Stratton 2001). This evidence further highlights the importance of the role of the oral cavity on the sensations of appetite and resulting food intakes.

Although oral exposure time was not measured in the current study, the period of time required for meal consumption in order to reach the point of satiation for each meal type was measured. It was demonstrated that the time taken for consumption did not significantly differ regardless of the form or energy density of the meal. It is interesting however that a trend was appearing reflecting longer times for consumption of the standard texture meals, which perhaps was due to additional chewing required for these. Although as the meals were consumed ad libitum and subjects tended to consume a greater quantity (g) of test meal in the standard texture form compared to the texture modified form, this may in fact account for the longer time taken to consume those meals. Also, the current study was not powered to detect differences in consumption times between the meals (but rather to detect

differences in energy intakes, chapter 3, section 3.3.2) which may have contributed to a non-significant result.

Other studies have demonstrated oral exposure time to be a factor contributing to eating behaviour (de Wijk et al. 2008; Zijlstra et al. 2009; de Graaf 2012). Those consuming a TMD may have longer oral exposure times as the condition is often characterised by a delay or misdirection of the bolus moving from the mouth to the stomach (Groher and Crary 2010). Additionally, the mastication ability of the individual can also affect the time food spends in the oral cavity, with poorer control possibly leading to longer residence times. In some, there may also be a fear of swallowing, due to the increased risk of aspiration (DeLegge 2002) which may further extend the time the food spends in the oral cavity.

These possible longer oral exposure times in patients with dysphagia and mastication difficulties may be implicated in the lower intakes often observed in those receiving a TMD. The elderly will also likely have longer oral exposure times compared to younger subjects (Forster et al. 2011) and this factor may impact on food intakes. The fact that healthy individuals were being investigated in the current study may also partially account (along with the small increases in quantity (g) consumed of these ST meals as discussed in section earlier) for the lack of difference in time for consumption of the ST and TM meals, as typically TMD meals are issued to facilitate intakes in those who may struggle to control their food in the oral cavity.

Although differences in energy (kcal) and food intakes (g) in the current study were observed, no differences in rated appetite parameters between meals of varying form

were found. This suggests that food intakes, which were reduced with texture modification, were not in line with appetite responses, which showed no difference between the meals of altered texture. In the current study, appetite ratings were assessed by VAS, as is the standard procedure for measuring subjective appetite (Blundell et al. 2010). These are susceptible to error (Stubbs et al. 2000), however it should be commented on that the error associated with the VAS in the current study was small (chapter 4, Figures 4.6 (a-c) and 4.8), and therefore the inconsistency between appetite responses and food intake previously discussed is unlikely to have been solely due to errors in measurement. It should also be considered that the current study was not specifically powered (chapter 3, section 3.3.2) to identify differences in appetite responses which may have contributed to the lack of detection of differences.

Other studies conducted in a healthy subject group with undisturbed appetite, have however demonstrated that texture can affect subjective appetite profiles, particularly for fullness (Marcini et al. 2001; Zijlstra et al. 2009). Perhaps differences in appetite responses (between the meal conditions) were not observed in the current study, because the extremes of the different textures examined were smaller (although not objectively measured) compared, to the studies by Marcini et al. (2001) (0.06 Pa. s (watery) and 29.5 Pa. s (barely pourable)), and Zijlstra et al. (2009) (0.085 Pa. s and 0. 788 Pa. s). After all, it was demonstrated by Marcini et al. (2001) that antral volumes increase with high viscosity meal compared to a low viscosity meal of equal nutrient content. This demonstrates that higher levels of viscosity stimulate gastric

distention, which can lead to reduced intakes (Geliebter et al. 1988; Rolls et al. 2000).

Whilst the test meal in the current study differed in texture (semi-solid versus soft-solid) the differences between the test meals were likely to not be as large as the differences in the foods studied above (Marcini et al. 2001; Zijlstra et al. 2009), however were more representative of a TMD meal (“Texture C” and “Texture E” categories) compared to the foods studied in these aforementioned studies. No standard objective measurements are provided for foods within the UK to give an idea of the range of viscosity for these therapeutic meals (chapter 1, section 1.4.1). In fact, there is a group working to develop standardised terminology of texture modified meals (Cichero et al. 2013) including objective measurement, although the project is at an early stage.

Another factor which may have resulted in similar appetite responses between the meals was the mode of consumption. In the current study, this was the same regardless of the form of the test meal (both meals were consumed using a fork via self-delivery, *i.e.* no peristaltic pump). This may have contributed for the lack of difference in appetite responses with different forms, especially since de Wijk et al. (2008) demonstrated that after the confounder of ‘bite effort’ is eliminated, solids and liquids are found to be equally satiating. Whilst the satiating effects of liquids were not being investigated in the current study, it is possible that this mechanism of bite effort may also play a role in the development of satiation for foods. In the current study the forms of the meals matched the consistencies of either “thick smooth puree” (Texture C) or “soft easy chew”, therefore the amount of bite effort required to consume these meals was unlikely to be extremely different. This small

difference in bite effort required for either meal may have further led to the lack of differences in appetite responses.

Leading on from the proposal by Zijlstra et al. (2010), it is also possible that as healthy individuals with normal chewing ability, were studied that the oral exposure time (unaffected by disease state) was too short (although not specifically measured) to incur a noticeable difference in appetite responses with altered texture. Interestingly in a study by Flood and Rolls (2007) (chapter 1, section 1.6.2), there was no difference in appetite responses in healthy adults between different forms of the same soup; however there was also no difference in the time taken to consume the soup, suggesting similar times of oral exposure.

Despite lack of statistical significance in appetite responses between the meals in the current study, there are trends in the data appearing over the one hour testing period. Such trends include hunger, and desire to eat ratings increasing after subjects served themselves a portion of the test meals in the ST form; however this increase was not observed after serving the TM meals. Fullness ratings showed no differences in trends between the meals of different textures, with all meals seeing a decrease in fullness after serving the meals. These trends could be interpreted to suggest that the appearance of the meal in their texture modified forms (after serving on plates) was sufficient to cause a decrease in both desires to eat and hunger even before consumption of the test meals.

This could suggest that provision of a texture modified meal can lead to reduced desire to eat as these meals can perhaps appear unappetising (SIGN 119 2010). It has

after all been demonstrated that when evaluating patient's perception to hospital food; appearance of the meal itself is important within the overall meal presentation (Stanga 2003). Additional effort may be required when presenting a TMD to promote intakes. Improved presentation has been demonstrated to enhance intakes of pureed meals in the past (Cassens et al. 1996). It is interesting to note that fullness ratings consistently decreased after the meals were served, but prior to consumption perhaps indicating the initiation of the digestive process via the cephalic responses to the food which can stimulate gastric sensations of appetite merely through the sight of food (Powley 1977). This further demonstrates the importance of consideration to the overall experience of eating, not just the post ingestive consequences which impact on eating behaviour.

As texture modification can negatively impact on food and consequently energy intakes strategies such as enrichment to potentially improve intakes in those receiving these meals are justified. In the current study, whilst it was observed that increasing the energy density of the test meals (both the ST and TM meals) had a significant effect on the nutritional composition of the meals (chapter 2, section 2.2.2, Table 2.6), with the enriched meal containing 40% greater energy per portion than the standard energy meals; there was no effect on absolute food intakes (g) consumed at the testing session. Consequently, due to the greater energy density (kcal/g) of the enriched meals (1.4 kcal/g versus 1.0 kcal/g), the resulting energy intakes (kcal) were significantly greater at the enriched meal occasions (ST and TM). Furthermore, no statistical difference in any of the measured appetite responses was observed between the meals of different energy densities in the current study.

Perhaps this lack of difference in appetite ratings during the testing session is why a difference in the quantity of food consumed (g) at the testing session (between meals of altered energy density) was also not observed. Therefore, the effectiveness of enriching both a ST and a TM meal for improving within meal energy intakes is clearly demonstrated in the current study. Before now, this strategy of enrichment for improving energy intakes has not been previously demonstrated in meals suitable for serving within a TMD. However these findings are not entirely surprising as it has been demonstrated that certainly in healthy individuals, the body's ability to regulate energy intake is more sensitive to volume and portion size than to that of energy density (Rolls et al. 2004; Roe et al. 2012). Previous studies have also confirmed that energy density can be altered without any acute effects on appetite responses, once the same portion is consumed (Mazlan et al. 2006).

It has in fact been suggested that energy density and portion size act synergistically to affect energy intake (Rolls et al. 2004) (chapter 1 section 1.6.2). However the subjects in the current study consumed the test meal ad libitum therefore they self-decided and thus had control of the portion size they consumed. Interestingly though, despite the fact that the subjects in the current study had complete control over the volume of food consumed, it was found that enriching the test meals (in ST and TM forms) did not result in significant differences in absolute food intake. This indeed demonstrates that the body appears to be more sensitive to volume and portion size rather than to energy density.

Despite the lack of statistical significance in appetite responses between the meals of varying energy density, there are trends in the data appearing. Such trends include higher hunger ratings after time point 6 (30 mins) for the standard energy meals in

both forms alluding to the fact that the meals of lower energy density (1.0 kcal/g versus 1.4 kcal/ g) induced a lower effect on satiety. Also after time point 6 (30 mins) ratings for desire to eat were lower with consumption of the enriched meals compared to standard energy meals.

These trends may indicate that the energy density of the food had a small impact on appetite with the more energy dense meal resulting in lower ratings for hunger and desire to eat after satiation was reached. As this trend was appearing at 30 minutes it is possible that this was due to activation of mechanoreceptors and chemoreceptors in the intestine and actually if responses had continued to be measured, a significant difference may have been observed, once the post-absorptive feedback was fully initiated (chapter 1, section 1.5). Rolls (2009) suggests too that within a meal, the physiological cues associated with differences in energy density may not have time to be engaged such that intake is determined by more immediate cues such as the amount consumed. The alteration in energy density therefore may have more likely caused an effect on period of satiety or subsequent energy intake once this post absorptive feedback had been initiated.

This was however not demonstrated in the current study. The period of satiety (as measured by the time from satiation at the test meal until the next eating occasion of >100 kcal) was not different between the test days. It should be mentioned that this outcome was not what the study had been powered on. Although a trend was appearing such that the time until the next eating occasion was longer after consumption of energy dense meals compared to standard energy meals. This perhaps reflects the additional energy consumed from the ED meals at the test meal eating occasion.

It was identified that there are a lack of studies investigating the effect of energy density of a full meal on the period of satiety. This is because most studies in this field tend to use a preload study design whereby a predetermined time interval after the preload up until the test meal is consumed is adopted. For example the study by Flood-Obbagy and Rolls (2009) which used the preload design required subjects to consume the fruit preload (in various forms) in its entirety followed by provision of a test meal to be consumed ad libitum 15 minutes later.

The current study however allowed subjects to consume the test meal ad libitum after which they were free to consume any food as they wished outside of the laboratory. Therefore the length of time between the preload (or in the case of this current study, the test meal) and subsequent intakes was different and thus different mechanisms of food intake regulation (*i.e.* within the satiety cascade (chapter 1, section 1.5, Figure 1.2) are likely to be coming into play. It is however argued that the current study had more real life relevance for measuring satiety, as subsequent food consumption was not dictated (food choice/time of consumption) by study design, but instead by individual motivation.

In the current study subsequent food intake was measured using an estimated diet diary. Despite its popularity for assessing dietary intakes, the diet diary does have limitations which should be acknowledged. Dietary record keeping requires that respondents be both motivated and literate, which can potentially limit use of this method in some population groups (Thompson and Subar 2008). Furthermore, maintaining diet diaries tends to interfere with the daily lives of subjects, altering dietary habits so that they no longer represent true habitual intake. Despite its limitations, the diet diary is a quick, cheap and uncomplicated method which is

successfully used to measure dietary intake. In this study, participants were required to keep four individual one day diet diaries with a minimum of three days in between each test day to avoid testing fatigue and the potential of a confounding carryover effect. All diet diaries were checked for completeness and follow up phone calls were made to clarify any unclear information such as food brands and portions sizes when necessary.

Studies involving biomarkers suggest that studies using food records or recalls are biased (on average, towards under reporting) and that individual may systematically differ in their reporting accuracy (Kipnis et al. 2001). This could mean that all dietary reporting instruments involve bias at the individual level. Use of a repeated measures cross over design along with following a standard operating procedure (SOP) controls for any level of bias at the individual level. With respect to the risk of subjects underreporting their dietary intake in the current study; as a standard breakfast was consumed followed by a strict fasting period (four hours) until the test meal, where the researcher recorded all intakes. Therefore the opportunity for under reporting existed only for meals consumed after the test meal therefore data regarding satiety and energy consumption would be at risk of error as a result of under reporting.

Although there was a reduced opportunity by the imposed study design to misreport energy intakes, the accuracy of the dietary reporting method was assessed (chapter 3, section 3.5.3). The detection of misreporting in the current study served the purpose to investigate the validity of the dietary data obtained. Based on the methods described in chapter 3 (section 3.5.3) it was attempted to check the accuracy of the dietary reporting methods used in this research; namely an estimated diet diary. A

full breakdown of each individuals estimated energy requirements (*i.e.* BMR x PAL (calculation explained in chapter 3)) and the differences in reported daily values can be seen in Appendix 14. Using the Goldberg method (Goldberg et al. 1991) to establish requirements, it appeared that potentially 48% of subjects consistently under reported their intakes, and 6% consistently over reported their intakes. The remaining 46% had no consistency in their misreporting (amount, and direction (*i.e.* under and over reported)).

Despite the apparent possibility that some individuals may have misreported their post-meal intakes, due to the flaws associated with this method reviewed elsewhere (Livingstone and Black, 2003) and additional uncertainties introduced by the current study design, this remains unclear. In the current study it is likely that the method used to accurately derive individual requirements, and individual activity levels were inaccurate. The fact that energy expenditure was not directly measured likely resulted in the derivation of incorrect predicted energy requirements. It should also be considered that prediction equations used are population based and therefore may not accurately reflect individual values.

Also, as weight status was not an outcome measure of this specific research and therefore was not measured at the end of the experimental period, it is unknown if the individuals were in energy balance. Another issue may be the fact that the individual's habitual dietary practices were being interrupted, with the research protocol dictating fasting between breakfast and lunch, consumption of a main meal at lunch time, as well as avoiding alcohol intake, all of which may impact on the amount of energy consumed.

Due to the uncertainty of the Goldberg method ($EE = BMR \times PAL$) and potential flaws associated with the current study for estimating requirements, the validity of the diet diaries cannot accurately be determined, and thus it was assumed that individuals reported intakes accurately. Studies which are specifically investigating weight status would however need to use more accurate measures such as directly measuring BMR, and measuring physical activity to better determine PAL factors.

The time until the next eating occasion (*i.e.* induced period of satiety) was also similar regardless of the texture of test meal indicating that in this current study texture did not significantly influence satiety, just satiation. This is not surprising because as discussed (chapter 1, section 1.6.2), texture has previously been implicated in satiation (Zijlstra et al. 2010).

It should be noted here that a difficulty encountered in the study was correctly defining the period of satiety. As the concept of meals and snacks can differ amongst the population, and may be dependent on individual situations (Wansink et al. 2010) it is therefore difficult to define “the next meal occasion”. It was decided to quantify the next eating occasion by a certain intake of calories (kcal) as this could be standardised easily amongst all participants. A similar study had defined the next eating occasion as >100 kcal (Mattes and Campbell 2009), therefore this was also chosen as the cut off in the current study in order to allow us to make comparisons. This study conducted by Mattes and Campbell (2009, discussed in detail in chapter 1, section 1.6.2) also demonstrated that there was no difference in the time interval from the consumption of either solid or semi-solid apple until the next eating

occasion (defined as >100 kcal as per our study) regardless if it was consumed as a preload or as a snack.

Despite the fact that the period of satiety did not differ, it may have been expected that subsequent intakes (*i.e.* post-meal energy intakes) after the standard texture meals in the current study would have been reduced later during the day compared to intakes after consumption of the texture modified meal. Previously discussed studies conducted in healthy subjects (chapter 1, section 1.6.2) (without presence of a swallowing disorder) have demonstrated that fruit in its solid form promotes greater feelings of satiety (Flood-Obbagy and Rolls 2009; Mattes and Campbell 2009), and significant reductions in subsequent energy intakes (at a test meal) (Flood-Obbagy and Rolls 2009) compared to its semi-solid (puree) and liquid (juice) counterparts.

This however was not observed in the current study; post-meal energy intakes were similar across the test days. Therefore regardless of the texture or the energy density of the meal consumed at the test meal, no significant differences in energy consumed after the test meal were observed. Furthermore, post-meal macronutrient intakes were not different between the test days. A high level of standard deviation was observed with mean breakfast, daily and post-meal intakes, however this is not unexpected. It is likely that this large level of variance reflects the variety within individual dietary patterns. After all, individuals consume a huge array of foods (and hence a variation in nutrient intakes) and these differ from day to day. This is also true for the large variation associated with intakes of breakfast, daily and post-meal micronutrient intakes.

The fact that post-meal intakes did not differ between the test days initially suggests that subsequent energy compensation did not occur. Investigation into energy compensation occurring after provision of the enriched meals, revealed that on average subjects only partially compensated by 15 % (ST) and 22 % (TM) which meant that daily energy intakes remained significantly higher after consumption of the ED meals for both ST and TM meals. This observed level of compensation does not denote under compensation, but rather an incomplete compensation. As described earlier, complete compensation is denoted by 100 % (chapter 3, section 3.5.7). This incomplete or partial compensation for energy intakes resulted in increased daily energy intakes of 14 % (260 kcal) for ST and 12% (225 kcal) for TM meals.

This demonstrates that enrichment at a single eating occasion can result in increased total daily energy intakes, with only small (15 %, 48 kcal (ST) and 22 %, 67 kcal (TM) post-meal adjustments in energy intakes. These findings are not entirely unexpected since it is established that fat content can drive overconsumption (Blundell and MacDiarmid 1997; Warwick et al. 2003; Erlanson-Albertsson, 2005; and Taha 2010), essentially resulting in delayed satiation. Yet as fat is documented to have a weak satiety effect (Rolls et al. 1988; Westerterp-Plantenga 2004), this over consumption observed within a meal (*i.e.* delayed satiation with fat), is unlikely to impact on subsequent eating occasions.

In summary, the current study demonstrated increases in test meal energy intake of 44% (315 kcal) and 47% (303 kcal) for ST and TM meals respectively. These

findings are in line with a study (Odlund Olin et al. 1996) which reported consumption of approximately 40% greater energy intake at a single meal occasion when it was enriched by 50%, also using store cupboard ingredients. It is interesting to observe that both healthy subjects in the current study and frail subjects (in the study by Odlund Olin et al. 1996), tended to achieve the same level of energy consumption when the diet was enriched to similar levels. Again, these studies support that fat content, and hence a high energy density results in a greater consumption of energy (kcal) within a meal. It should be emphasised here, that the purpose of food enrichment strategies are not to drive passive overconsumption of fat (and hence excess energy intakes), but rather these aim to make up for reduced energy intakes as a result of poor appetite and reduced food intakes (g).

As energy and macronutrient intakes consumed post-test meal did not significantly differ between conditions, and breakfast energy intakes were controlled between testing days, the observed energy increases can confidently be attributed to the energy density of the meals consumed at the lunch session. It therefore seems from the results of the current study that energy intake as a function of energy density is not regulated within a single meal. Therefore altering the energy density of a meal does not affect absolute food intake (g). Thus overall energy intakes are more related to the energy content of meal, rather than the amount of food consumed. Therefore identifying new feeding patterns reflecting individuals' sensitivity to volume but not to energy density should be examined further, particularly for those with poor appetites.

5.2 Application and considerations:

Overall this was a well-designed and well-controlled experimental study (Appendix 15) which was specifically designed to follow the essential methodological requirements to assess eating behaviour (Blundell et al. 2010), whilst also following guidelines in place regarding food provision in clinical settings (Chapter 2, section 2.1.3). Therefore much needed insight into the potential effectiveness of the strategy of using food based enrichment to improve energy intakes, (including both standard and texture modified diets), as advised in the clinical setting was gained.

The results from this study, conducted in healthy adults, clearly demonstrate that this strategy shows promise for increasing energy intakes (of both standard and texture modified meals) in this group. However it is acknowledged that this would need to be further evaluated in a clinical setting. The current study did however demonstrate similar trends of reduced intakes of a TMD (as demonstrated by Wright et al. 2005; Bannerman and McDermott 2009), and increased energy intakes with higher energy density (as demonstrated by Gall et al. 1998; Odlund Olin et al. 1996; 2003; Silver et al. 2008) despite being conducted in a well-controlled setting using a healthy sample group. There was however differences in the extremes of the intakes between the current study and what have been demonstrated in clinical settings.

Indeed, possible reasons for these differences must also be addressed when considering the application of the current study to the clinical setting. These may be due to difference in study design. For example, Wright et al. (2005) observed lower daily energy intakes (by 535 kcal) with provision of a TMD compared to a control group, receiving a standard texture diet. It should be considered that the current study

was investigating the impact of the provision of one meal (a main meal) which was altered by texture whereas other studies have considered daily intakes with all meals provided in forms suitable for provision within a TMD. Perhaps if food/energy intakes consumed from a TMD were evaluated over the course of a day in the current study, differences that are more in line with what has been observed in studies investigating daily energy intakes (Wright et al. 2005; Bannerman and McDermott 2011) may have been observed.

A number of other reasons discussed below are to be considered when drawing conclusions regarding the application of this strategy in the clinical setting. Such factors include; the additional impact on eating behaviour which include (but are not limited to); disease state, medications and psychological state, additional issues which may contribute to poor intakes (*i.e.* provision constraints), the realistic application of the findings from a study which was restricted by key design issues and experimental protocol, and a consideration to the contribution this single test meal can make within the context of the whole diet extended over periods greater than 24 hours.

Disease state, medications and psychological state:

It is proposed that a principle reason for the differences in the level of intakes consumed by those in the clinical setting and those in the current study is accredited to additional health issues (in those in the clinical setting) which could further complicate eating behaviour. This also implies that it is likely that there will be

differences in the extent of the additional energy intakes between the current study, and when applied in a population with health issues.

The healthy participants in the current research likely were recruited based on the fact that they had normal appetites (free from disease and appetite altering medications) and were shown not to be exercising dietary restraint. During illness however, anorexia is commonly experienced as a result of both physical and psychological factors (Stanga et al. 2003). Reduced appetite may be due to; illness (Richardson and Davidson 2003; Otero et al. 2005), lack of physical activity, and the consumption of medications (Stanga 2009). Further it is well established that the consumption of medications can promote additional adverse gastrointestinal effects such as nausea and vomiting, which will likely negatively impact on motivation to eat.

Appetite regulation may be further disrupted by the metabolic disturbance which accompanies illness and conditions associated with activation of the inflammatory response which can have profound effects on the neurophysiological mechanisms responsible for ingestive behaviour (Richardson and Davidson 2003) and therefore these factors may also impact on the application of the results. Furthermore, reductions in energy intakes may be even greater in a population with dysphagia. This has been demonstrated in the study by Ekberg et al. (2002) which showed that 55% of patients reported their dysphagia to affect their eating habits leading them to consume less, and avoid certain foods.

The impact of disease on appetite may contribute to the explanation of the lower intakes observed with provision of a TMD in the clinical setting. In the study by

Wright et al. (2005), although all subjects (control group, and texture modified group) were recruited from ‘medicine for the elderly’ wards (suggesting similar characteristics), the control group was described as being “medically stable” and therefore were likely not to be confounded by disease state to the same extent as the texture modified group. This may have contributed to the large difference in daily energy intakes (535 kcal) between the two groups.

Psychological aspects of eating, including the anticipation of food which may be altered by cognitive and sensory (visual, aromatic) characteristics of a meal are established factors which influence eating behaviour (Blundell et al. 1999), (chapter 1, section 1.5, Figure 1.2). In the current study these were specifically controlled, for example by following a single blind study design and by disguising the alterations made to the meal by serving them identically. It is however not clear from the current study, if similar alterations could be disguised when evaluating other meals, for example comparing a standard roast beef meal to a “Texture C” beef meal which would visually differ substantially. With respect to the influence of individual psychological influences on eating behaviour in the current study these were controlled by using the randomised, repeated measures design.

A consideration with regards applying these enriched meals for those prescribed a TMD in the clinical setting, is the disruption of learned associations made from prior exposures to foods. Those prescribed a TMD, particularly those who may be adults, have likely had extensive exposure to foods over their lifetime prior to being prescribed a TMD and have therefore developed learned associations to textures more in line with their expectations based on previous exposures (Mars et al. 2009). It is in fact reported that initially individuals are not familiar with the post-ingestive

consequences of a new food, however after repeated consumption an association may form between sensory characteristics of the food and its post-ingestive consequences (Mars et al. 2009). This may be a reason why those requiring a TMD can struggle with their intakes, as essentially they need to retrain their eating behaviour which they have previously established prior to prescription of this therapeutic diet. Perhaps however with repeated exposure of the modified foods, individual eating behaviour can be re-established, leading to intakes more in line with consumption of a diet that has not been texture modified.

Another consideration is the additional impact on psychological state on appetite in the clinical setting. Paykel (1977) demonstrated that in depressed individuals, 66% exhibited a decrease in appetite, 20% showed no change, and in 14% appetite was increased. Thus, to fully appreciate how the strategy of enriching these TMD meals for improving intakes in individuals with potentially altered appetite regulation, there is need for further investigation within the clinical setting.

Sensory Specific Satiety to texture:

Another consideration when applying the current study with respect to consumption of foods of altered texture in a clinical setting is that those prescribed a TMD would be receiving this same type of texture for all meals and it may be possible that sensory specific satiety (SSS) to texture occurs. As discussed in chapter 1, (section 1.5), SSS is a phenomenon in which there is a reduction in the subjective pleasantness of the taste, smell, appearance, and texture of a food as it is eaten relative to uneaten foods occurring during a single eating episode (Nolan and

Hetherington 2009). It has in fact been proposed that intakes will be greater if foods within a meal vary in their sensory characteristics (Raynor and Epstein 2001).

Similarly it has been demonstrated that a longer duration or higher intensity of a sensory signal may promote satiation (Blundell et al. 2010). Foods of higher viscosity (of which certain TMD could be categorised for example) are said to provide longer orosensory stimulation (Mars et al. 2009) and this may contribute to sensory fatigue and early satiation or satiety. Meals with higher energy density may also stimulate a more intense sensory signal compared to a lower energy dense meal. It has already been demonstrated that higher energy preloads produce a greater sensory specific satiety compared to lower energy preloads (Johnson and Vickers 1993). Although it does appear that there is an oral fat detection threshold (Hoppert et al. 2012) and thus further supports the need for more studies to determine appropriate levels of enrichment which enables improved energy intakes, without suppressing appetite.

In the current study, compared to the ST meals, the rated palatability for the texture modified meals declined more rapidly (reaching significance for the TM ED meal, chapter 4, Figure 4.8) over the course of the session particularly between time point 3 (6 mins; when meal was first tasted) and time point 5 (20 mins; when the majority of subjects had reached satiation). This may suggest SSS to the meals occurred as demonstrated by the rated decrease in pleasantness of the meal due to becoming satiated to certain sensory characteristics of the meal. This SSS may be more pronounced with a TMD as all meals should be of the same uniform texture throughout due to the dietary prescription (BDA 2012a).

Decreases in rated palatability (over the meal session) were not observed with consumption of the ST meals in the current study, arguably supporting the SSS to texture within a TMD. The individuals in the current study were healthy and therefore not prescribed a particular texture diet out with the testing sessions. Therefore the subjects would not necessarily be fatigued to the same extent by receiving the same texture diet for all meals. In comparison to in practice and in cross sectional studies which include patient groups already following a TMD, sensory fatigue to texture may occur over time impacting on food and energy intakes. It was perhaps the initiation of SSS to texture that led to patients in the study by Ekberg et al. (2002) reporting that they tend to consume less food than prior to prescription of TMD despite reporting to feel hungry.

Considering the possibility of SSS to texture occurring, it is hypothesised that this is likely to occur also across all meals further impacting on intakes overtime. If this is the case, it is important to attempt to offer variety to the meals in other ways. For example the inclusion of different flavours and tastes, and perhaps altered meal patterns to offer more variety in eating behaviour which may help to reduce any risk of SSS incurred by providing meals of the same texture.

One consideration with regard SSS is that the observed decline in SSS with advancing age (Rolls and McDermott, 1991) discussed in chapter 1, section 1.5). This has previously been attributed to causing older individuals to limit their food intake particularly in terms of variety, potentially resulting in nutrient deficiencies. Although this reduction of SSS observed with advancing age is normally considered a barrier to achieving a balanced and varied diet; for those receiving a TMD this phenomenon may actually help with ensuring long term compliance to a TMD in

older adults. All foods within a TMD are produced to meet specific textural categories (BDA 2012a) therefore those with a decline in SSS are likely less fatigued by receiving the same texture category for all meals than those more sensitive to SSS.

Additional factors attributed to reduced food intakes in the clinical setting.

Institutional catering providers face a range of challenges with food provision in the hospital setting. These were addressed previously (chapter 1, section 1.3.3) and indeed remain a concern with regards to achieving adequate energy intakes with the provision of enriched TMD meals. However, the wider issues that can affect patient food intake need to also be assessed when considering the application of the enrichment of meals, including TM meals for improving energy intakes.

The diverse needs of the hospital population remains a challenge and the menus offered need to reflect the population it aims to serve. The guidance followed (Scottish Government 2008) in the current study addressed the diversity of nutritional needs within the hospital setting by developing two sets of nutrient-based standards. These aim to cater for patients who are ‘nutritionally vulnerable’ (those with poor appetites, increased risk of malnutrition) and those who are ‘nutritionally well’ patients. Recommendations for provision (energy and protein) for both of these were followed during the development of the test meal (Chapter 2, section 2.2), thus are arguably suitable for a range of patients (both ‘nutritionally well’ and ‘nutritionally vulnerable’) in the hospital setting.

Food provision however not only needs to meet individual nutritional requirements, it also needs to be appropriate for different age groups, religious, cultural and social backgrounds as well as for different medical conditions. Based on the composition and ingredients used in the test meal in the current study it is acknowledged that this meal will not be suitable for consumption by all. Table 5.2 outlines those who may not be able to consume this meal in its current formulation.

Table 5.2: Those identified as not being suitable for consuming the test meal

Patient group	Reason for non-consumption of meal
Those with a texture modified diet prescription outside of Texture E or Texture C	Provision of meals that are not of prescribed texture could lead to aspiration and/or reduced intakes.
Those sensitive to allergens	Of those legally required to be declared as an allergen; milk based products are included in this meal. Thus those with milk allergens cannot safely consume this meal.
Those following a renal diet	This meal contains: >47 mg of potassium and >60 mg sodium per meal.
Those consuming monoamine oxidase inhibitors (MAOI) for treatment of depression	Due to the disruption in the metabolism on tyramine, foods containing tyramine should be avoided. Those specifically listed include, gravy granules and meat based stock cubes both which are included in the test meal.
Vegetarians and vegans	The test meal is meat based and contains milk products.
Those following the Halal diet	Not clear if the meat used was slaughtered by Halal methods.
Those following the Hindu diet	The cow is considered sacred, therefore beef consumption is rare.
Those following Kashrut law	This is the prohibition of mixing (<i>i.e.</i> the cooking and/or consumption) of meat and milk products. Both are included in the test meal recipe.

Source: Scottish Government, 2008.

Another consideration is that there is a large amount of food waste associated with hospital food provision (Barton 2000). This could be attributed to patients struggling

to consume food which may be related to physical difficulties for achieving food consumption, or alternatively that the food provided is not of adequate quality. This is particularly true of TM meals which are typically poorly received by patients. Assistance with eating falls within the PMI (discussed chapter 1, section 1.3.3) and it is agreed that this strategy should be adopted alongside the strategy of increased energy provision in an effort to maximise the opportunity for adequate food consumption.

Of arguably equal importance, is the provision of meals that patients rate to be enjoyable. Palatability was a key consideration during the development of the meal (chapter 2, section 2.1.2) and it was found that the meal in the current study was rated to be palatable in all versions. Despite the palatability of the TM meals being reduced these were still rated as acceptable (>50 mm VAS). In practice however, there appears to be a lack of consultation with patients about the aesthetics of their meals. In a recent audit in Wales it was found that only three health boards said that they have regularly carried out food-tasting panels involving patients. This means that many NHS bodies are missing an opportunity to obtain useful feedback about specific issues that are important to patients in relation to the taste, texture and presentation of food (Wales Audit Office 2011).

When catering departments were visited during the design of the current study low levels of plate wastage were reported. It was however expected that this value would be higher, especially due to the high prevalence of malnutrition in hospitals. However it became clear that the method that the catering department used to assess “plate wastage” was not conducted at ward level (*i.e.* the amount of food consumed as a percentage of what was served) but instead, marked as the number of meals left

untouched completely. This reflects that patients may not have been available or able to consume their meal rather than the quality and acceptance of the meals. It appears that it is the kitchen level plate wastage that is reported back to Government which is potentially misleading as it does not demonstrate much about actual hospital food consumption. Rather than disregarding food based methods for improving intakes in hospitals, more attention should be given to the quality and aesthetics of food produced and this should be done in consultation with patients for whom the food is aimed to serve.

Study design restrictions and their impact on application

This study was specifically designed to control for the introduction of confounding variables (discussed in chapter 2, section 2.1.2). However when considering the potential application of the findings in a clinical context, the restraints in place as a result of following a controlled experimental design need to be evaluated. Most notably, the current study was mainly conducted in a controlled laboratory setting which is not representative of how food would be consumed in a clinical setting, often at bedside or in canteens. The discussed cross sectional studies which were conducted in a clinical setting (for example the study by Wright et al. 2005) perhaps more accurately represent what actually occurs in clinical practice. However, as reviewed earlier the study design used in these was less controlled than in the current study. Similar concerns exist in studies investigating enrichment in the clinical setting (Gall et al. 1998; Odlund-Olin et al. 2003). For example these studies used unpaired study designs thus introducing a range of inter-individual confounders.

The current study however attempted to meet the requirements of hospital food provision as much as possible without compromising the study design (chapter 2, section 2.1 and chapter 3, section 3.2). This not only included following the guidelines for meal development, but also replicated service provision in hospitals, whilst using a randomised crossover design. The current study used the cook-serve method of production, and bulk service delivery of a meal that is typically offered and within usual budget constraints within the hospital menu. It is however acknowledged that this may however not be a feasible method of food provision in all sites. The size of the catering facility and also the method of food production, for example whether it is on-site or out-sourced, will further impact on the scope of service that different establishments can provide.

Subjects in the current study were weighed to determine that they met the inclusion criteria before enrolling in the study. Weight status was however not an outcome measure in the study; therefore change in weight from the start of the study until the end of the study was not measured. However, significant (clinically) changes in weight (*i.e.* >5 % body weight (Stevens et al. 2006)) may have contributed to an alteration in the regulation of energy intake since pathways involved in this mechanism have been shown to differ with weight status (Ranganath et al. 1996; English et al. 2002; Batterham et al. 2003) (chapter 2 section 2.1.2).

It is however unlikely that significant changes in weight status occurred in the current study as most participants completed the study cycle in less than one month (median (IQR) 29 (21, 35)). Furthermore, subjects recruited to the study were required to exhibit normal eating behaviours (*i.e.* not exercising restraint) and not to be following any therapeutic or weight management diet. Any change in weight over

this period is likely to be small and be within the normal range of weight fluctuations. Stevens et al. (2006) recommend a definition of 3% weight change to indicate weight maintenance. In the current study that roughly translates to approximately 2 kg (based on the mean weight of subjects, chapter 4, Table 4.1).

The current study evaluated short term intakes, over one day periods and therefore it cannot be assumed that apparent improvements in energy intake with enrichment would be observed over longer periods. Studies which have investigated the impact of energy density over longer periods have done so with the focus of reducing energy density for purposes of weight management (Rolls et al. 2005; Ello-Martin et al. 2007; Lowe et al. 2008). Long term studies of this nature are difficult to control however end of trial weight status may be used to determine the effect of dietary energy densities on intakes (Westerterp-Plantenga 2004).

There are likely to be other mechanisms which will influence individual eating behaviour and thus the success of interventions involving the alterations of energy density, which may become more apparent in studies of longer duration. For example Westerterp-Plantenga et al. (1998) demonstrated that the long term (6 months) impact on weight status was further dependent on the level of restraint of the individual (Westerterp-Plantenga et al. 1998) and this must be considered when applying strategies to improve energy intakes long term. It is largely unknown if the provision of high energy dense meal over longer periods will result in altered eating behaviour in order to regulate weight status.

One study demonstrated that CCK sensitivity to fat did not change after two week exposure to a high fat diet (Tai et al. 2010). Perhaps differences in the regulation of

eating behaviour would appear over longer periods however. A longer study (eight weeks) demonstrated that subjects who consumed high energy dense snacks with their meals had a significant increase in body weight during the study (+ 0.6 kg; $p=0.004$), whereas those who consumed low energy dense snacks between or with meals or high energy dense snacks between meals did not have significant changes in body weight during the study (Viskaal-van Dongen et al. 2010). Whilst this was a statistically significant increase in weight it is unlikely to have clinical significance. It does however demonstrate that long term provision of energy dense components of the diet may contribute to weight gain. Carrying out similar studies over longer periods with a larger selection of meals need to be evaluated with the purpose being to improve intakes. This will also allow greater meal choice which is important for ensuring a balanced diet with adequate intakes of all nutrients, and reducing the impact of sensory fatigue to certain meals.

It is also worth considering that the strategy of enrichment may have more success for improving long term intakes in older individuals, who have demonstrated a reduced ability to correctly compensate for energy with advancing age (Rolls et al. 1995a; Appleton et al. 2011). Perhaps these individuals will be less likely to reduce their subsequent energy intakes which may maximise any nutritional benefit achieved by the enrichment and/or supplementation.

Cost considerations:

Meals that are texture modified are often exposed to increased risk of waste due to the additional production steps they undergo, including; blending, sieving, and

moulding. Some weight of food may be lost during each of these additional stages of processing. In this study average losses were estimated to be 26% of total weight (chapter 2, section 2.2.1). Therefore to ensure the quantity of the product that was served was the same for both the standard and unmodified meals, the TM recipes were scaled up to allow for additional loss. The additional quantities of ingredients required for texture modification for this meal cost £ 0.22 per portion (390 g) for both standard and texture modified meals (chapter 2, section 2.2.3, Table 2.11).

Ensuring equal yields of the ST and TM meals was essential for this current study design and was therefore a key consideration during the design of all versions of the test meals. This same level of emphasis for making up for waste encountered during the production of a texture modified meal may not occur in the diet kitchen. It is not uncommon for costs to increase with additional texture modification. For example; increases of £0.99 are observed for the “Texture C” puree cottage pie compared to the extra tender cottage pie from Wiltshire Farm Foods (chapter 2, section 2.2, Table 2.12). These costs have been adjusted for weight, although the puree meal version provided an additional 61 kcal also. If in the clinical setting, texture modified recipes were scaled up to take account of potential losses endured during production as in this study, the cost of producing these meals would likely increase also. It should however be considered that not scaling the recipes to account for any nutrient loss during preparation of these meal could lead to increased care costs due to undernutrition as a result of reduced nutrient provision over time.

Enrichment is a strategy to make up for reduced provision, without necessarily increasing the portion size. As expected, in the current study due to the addition of ingredients (*i.e.* butter and cream) the cost of the test meal increased with energy

enrichment. The total cost of the enriched meals (ingredients only) was £1.04 (ST) and £1.26 (TM) per portion (chapter 2, section 2.2.3, Table 2.11). This falls within the estimated average amount of money spent of the cost of ingredients per patient per day in the hospital setting (£2.43 per patient per day- chapter 1, section 1.3.2). Arguably, the meal in the current study was prepared using ingredients that are typically less expensive. Therefore, enriched meals containing more expensive ingredients (fish based meals for example) may account for a greater proportion of daily food expenditure.

Compared to the SE meals, it was estimated that the cost of enrichment was £ 0.07 per portion for both ST and TM meals. This additional £ 0.07 resulted in an increase of 152 kcal (40% improvement in energy provision) per portion. However, it cannot be assumed that enrichment across all meals will cost the same due to the different types and quantities of ingredients used. Thus each individual enriched meal would need to be evaluated and costed in its own right. In the current study additional energy was provided via enrichment using spreads and cream. These ingredients are relatively cheaper than using other means of achieving similar increases in energy provision as indicated in Table 5.3. It is acknowledged that the additional costs of enrichment above do not include the additional cost of resources, such as staff time for additional stages of food preparation.

It should be considered that these store cupboard ingredients, not only offer the potential for increasing energy provision at a relatively low cost. They may also be more accessible for those seeking strategies for increasing energy intakes in the community setting. After all, malnutrition is not confined to institutionalised settings (hospitals and care homes), but also occurs in the community. Therefore strategies to

manage malnutrition need to be applicable in both community and institutionalised settings in an effort to reduce the high UK prevalence. This is particularly true considering the cost of ONS in the community setting, which can cost £3.00 per 220 ml /unit (330 kcal) (*Ensure*).

Table 5.3: Cost comparisons between ingredients and proprietary products used for enrichment

Food product	Cost per unit	Cost per ml/g	kcal per ml/ g	Cost per 100 kcal
Double cream	£1.68 (600ml)	£0.03 (ml)	4.6	£0.65
Spread (60% fat)	£3.00 (1 kg)	£0.003 (g)	4.1	£0.07
Spread (75% fat)	£3.70 (1 kg)	£0.004 (g)	6.8	£0.06
Cheddar cheese	£8.57 (1 kg)	£0.09 (g)	4.2	£2.14
Dried milk powder	£1.88 (340g)	£0.005 (g)	3.6	£0.14
Proprietary products	Cost per unit	Cost per ml/g	kcal per ml/g	Cost per 100 kcal
Calogen	£5.75 (200 ml)	£0.03 (ml)	4.5	£0.67
Polycal	£6.30 (400 g)	£0.16 (g)	3.8	£4.21
Ensure Two kcal	£3.35 (200 ml)	£0.02 (ml)	2.0	£1.00
Fortisip	£2.49 (200 ml)	£0.01 (ml)	1.5	£0.67
Fresubin	£3.05 (200 ml)	£0.02 (ml)	1.5	£1.33
Complan	£3.49 (228 g)	£0.02 (g)	4.4	£0.45
Build-up	£3.59 (152 g)	£0.02 (g)	3.4	£0.59

(Pricing information sourced from Nutridrinks.co.uk and mysupermarket.co.uk)

Further when the cost of the test meal ingredients was compared to similar available pre-prepared meals (e.g. cottage pie from Wiltshire Farm Foods), the meal used in the current study was considerably less expensive. As served, cottage pie (Texture C) provided by Wiltshire Farm Foods costs £4.60 per portion (430 g). When the cost was adjusted to be comparable to the portion of the test meal in the current study (*i.e.* 390 g) the calculated cost was £ 4.17 (TM) (excluding cooking time), providing 494

kcal per portion. Compared to the TM ED meal in the current study this pre-prepared meal costs an additional £2.91, whilst providing a deficit of 43 kcal (chapter 2, section 2.2.3, Table 2.12). This further demonstrates the potential of enrichment using affordable, accessible store cupboard items as a potentially more cost effective (kcal provision/ cost) solution for improving energy intakes, once of course the meals are consumed.

Nutritional profile of the test meal in relation to total diet:

The current study was evaluating the impact of enriching one meal (ST and TM forms) on eating behaviour in order to gain insight into the potential of this strategy for improving energy intakes, in a controlled setting. It is acknowledged that this one meal cannot meet all the requirements outlined for the provision of nutrients in the clinical setting. This one meal was however developed to specifically meet the guidance for meal planning standards (Scottish Government 2008). These standards have been set to assist caterers and menu planning groups to develop menus that will ensure both the dietary and nutritional needs of patients are met. These include standards for the provision of substantial snacks (twice a day); provision of a hot meal option both in the middle of the day and at the evening meal; standards for out-of-hours food provision; minimum ward-based food stock items; use of standard recipes for all dishes provided; guidance on nutritional analysis of recipes and also determination of menu capacity.

It has been estimated that to provide a menu that will enable the range of energy and protein requirements of patients to be met; that “a minimum of 300 kcal per main

meal and 500 kcal for an energy dense main meal, and 18 grams protein” should be provided. These recommendations for protein and energy were followed in the development of the test meals (chapter 2, section 2.2) in the current study and should therefore fit well within the context of a hospital menu.

The fibre content of the test meals may be considered relatively low, however typically those who are “nutritional vulnerable” tend to have poor appetites. Generally fibre rich foods require greater mastication (Salas-Salvado et al. 2006) likely extending the time these foods spend in the oral phase, which as discussed may induce early satiation leading to reduced intakes. Also viscous dietary fibres (*i.e.* soluble fibres) absorb large volumes of water, increasing stomach distension which may also trigger afferent signals of fullness (Kristensen and Georg Jensen 2011). As such, a diet that is very high in NSP is not advocated for individuals with a poor appetite where the aim is to ensure maximum food and thus energy and nutrient intakes. It is recommended that diets of ‘nutritionally well’ adults should contain 18g/day; with a range 12-18g for the ‘nutritionally vulnerable’ depending on individual circumstances. Within a TMD fibre content of the diets is variable. Often foods with large amounts of fibrous material are excluded from the diet as they do not meet the dietary prescription (as encountered in the current study, chapter 2, section 2.2, Table 2.4).

If reduced appetite is not a concern, perhaps patients may be prescribed fibre supplements. That being said however, increasing the fibre content (through supplements or through diet) will also lead to increased water requirements, which is often limited in those receiving a TMD. On the other hand, often during the preparation of fluids for TMD, fibre based thickeners (e.g. Nutilis (Nutricia)) are

added to facilitate safe consumption without aspiration. These fibre rich beverages may have a highly viscous mouthfeel which is linked to inducing feelings of fullness (Mattes and Rothacker 2001). Furthermore increases in satiation and satiety may be induced due to increases in gastric distension and delayed gastric emptying.

For those who are “nutritionally vulnerable” there is no guidance regarding the proportion of daily energy that should come from fat. Essentially this is to allow the manipulation of the energy density of meals for provision within these diets. The meals in the current study were enriched through the addition of fat based ingredients. It should be considered that the long term consumption of such fat based, energy dense meals goes against current public health recommendations for the general population, and the “nutritionally well” in hospital (Scottish Government 2008) (chapter 2, section 2.2.2, Table 2.6) who are generally advised to restrict their fat intake to less than 35 % of total energy, with < 11% of total energy from fat coming from saturated sources. The enriched test meals (ED) in this study contained 55 % energy from fat of which 22 % came from saturated sources thus if these meals were consumed on an ongoing basis by the general population, may actually result in increased risk of becoming overweight or obese consequently developing related conditions such as cardiovascular disease and certain cancers (WHO 2002).

Despite their trial in a healthy sample in the current study, these meals have not been developed for consumption by the general healthy individual or the “nutritionally well” individual (Scottish Government 2008). In fact these meals were developed for potential application in the nutritionally vulnerable, including potentially those with mastication difficulties or dysphagia requiring a “Texture E” or “Texture C” diet, who may be struggling to meet their energy needs. It is argued that for these

individuals, the risk of malnutrition and associated complications are a greater concern than the development of the aforementioned obesity related conditions (*i.e.* CVD) and therefore optimising the energy intake may become a priority. A study conducted by Gariballa et al. (1998) investigated the influence of nutritional status on clinical outcome after acute stroke and found that stroke patients with hypoalbuminemia had a greater risk of developing infective complications than those with normal or higher serum albumin levels. It should however be considered that albumin is a marker of disease and is not nutrition specific therefore this should be interpreted cautiously.

It may therefore be that enrichment be adopted as an initial management technique to improve energy intakes, which could hopefully contribute to improved weight status and perhaps reduce the risk of associated complications such as infections. As a majority of patients with dysphagia (as a result of stroke) typically recover their swallowing function within the first month after a stroke (Corrigan et al. 2011) it is unlikely that this relatively short term intervention of enrichment will contribute to the development of obesity related conditions. For those who typically continue to experience a deterioration in swallow function (e.g. for those with degenerative conditions such as MND or MS), other means for encouraging intakes would need to be evaluated. It is likely in these cases that eventually artificial feeding methods will need to be introduced.

Perhaps for those who can tolerate oral nutrition, further investigations into developing meals which may contain more health promoting ingredients that may act for secondary prevention of certain conditions may be particularly relevant in the dysphagic population, many of whom will have this condition as a result of a

cerebrovascular incident (stroke) of which diet is implicated in its occurrence (WHO, 2002). A recent review conducted by Apostolopoulou et al. (2012), evaluated the dietary implication of stroke (primary and secondary) and found that there are no reported studies of the effect of dietary changes on the secondary prevention of stroke (*i.e.* stroke as primary outcome). However they reported that the Oslo Heart Study (Leren 1970) demonstrated a 13 % decrease in total cholesterol in an experimental group (men who had suffered myocardial infarction) following a lipid lowering diet. LDL cholesterol is associated with increased risk of stroke (WHO 2002); by increasing atherosclerosis risk and therefore reducing this may help with secondary prevention. This perhaps highlights that those prescribed a TMD as a result of stroke, be prescribed meals that have been enriched using ingredients, other than saturated fat (which may raise total cholesterol) that may aid in secondary prevention.

As this study was looking at one meal, and guidance regarding provision of individual meals relates solely to energy and protein (the main focus of the current study), the micronutrient content of the test meal was not specifically considered during the development of the meal. Further, the guidelines surrounding provision of micronutrients (Scottish Government 2008) is based on the recommended DRVs. These values are recommended to be met, on average, over the period of one week. It is unlikely that a free-living individual at home will meet the RNI for all nutrients on a daily basis (let alone at an individual meal occasion) with most being met on average over a week, reflecting the recommendation.

The test meal in the current study would be offered alongside additional courses (*i.e.* sides and dessert) and additional meals (breakfast, dinner and snacks) however it

alone was found to contribute considerably to the requirements for most nutrients. For some (vitamin A and B₁₂) the consumption of a portion of the test meal results in the recommended daily needs being exceeded. The test meal alone however is low in other nutrients (particularly vitamin D, calcium) and these should be sought to be met by the diet elsewhere. It was also acknowledged that these recommendations were developed specifically for use with healthy groups of the population and may not reflect the needs of individual patients. Nonetheless, the micronutrient content of the test meal needs to be considered within the application, and within the context of the total diet. Key micronutrients which have important relevance for the hospital setting are considered below.

Vitamin A is important for hospital patients. At appropriate doses, it is essential for epidermal proliferation and re-epithelialisation through the binding of retinol (the active form of vitamin A) to cell surface receptors (Brown and Phillips 2010). Thus deficiency can decrease integrity of skin and mucous membranes, increasing risk of infection. The test meal in the current study exceeded the requirements for this nutrient. Thus the menu planning team should take this into account when building menu options as this vitamin can become toxic at large levels (hypervitaminosis A).

As a cofactor for collagen synthesis vitamin C is important for hospitalised patients as adequate levels are required to assist in wound healing (Wild et al. 2010). The test meals provided almost 60% of daily needs for this nutrient, and it is likely that additional requirements would be met through additional meals throughout the day. Toxicity is not a huge concern with this vitamin as excess vitamin C is excreted, although may lead to some discomfort. Adequate zinc is important for hospitalised patients as it is required for optimal wound healing for patients who have suffered

trauma, had surgery or have a wound or pressure ulcer (Brown and Phillips 2010). In fact it is reported that low zinc status decreases closure and draft pressure of the wound and suppresses the inflammatory process (Wild et al. 2010). The test meal provided almost 50% of the recommended daily needs, which is a large proportion of daily requirements, considering this came from one portion of a single test meal.

Of some concern are the relatively low concentration of calcium and vitamin D, and the high concentration of sodium. It may be particularly important to monitor sodium intakes in this group particularly as many patients with dysphagia experience the condition as a result of a stroke, of which a high intake of sodium may contribute to (Sanghazi and Vassalotti 2013). It may be necessary to redesign this meal to reduce the sodium content for use in some patients. It did appear that the majority of the sodium was coming from the stock cube, gravy and Worcester sauce, which were mostly added for flavouring purposes contributing little energy to the meal. These ingredients are however important to ensure the meals are aesthetically pleasing, such that the meal is actually consumed. Perhaps use of reduced sodium products would be more appropriate for provision in this group.

The test meal was also found to be low in calcium, contributing just 10% of the recommended daily intake. There are only a few studies specifically linking this nutrient to wound healing however as it is a cofactor and regulator in many soft tissues, (including skin) (Phillips and Brown 2010), it is not unreasonable to assume it can play a role. Again, as this is just one meal it is likely that provision of other meals will provide additional calcium. It may be for example that this meal be served alongside a milk based pudding. The test meal is also low in vitamin D, which in fact is a common nutrient deficiency in the UK (Department of Health 2012c). Most

people can make their own vitamin D however in the hospital setting, where sunlight exposure is limited, other means such as supplementation may be warranted. Currently, every person aged >65 years in the UK is eligible for a vitamin D supplement (SACN 2007), therefore deficiency in these individuals is less of a concern.

It should be considered that the nutrient content of the test meals was estimated using data from raw ingredients (chapter 2). Thus, it is likely that in actual fact, the content of some micronutrients will be reduced during processing. In fact changes in micronutrient content with heat (*i.e.* cooking) and blending is well recognised. These factors may support the use of supplementation, with nutrients other than vitamin D, alongside other food based strategies in those at risk of poor intakes.

Additional application: weight management

Although this specific research focused on the application for maximising intakes for potential use in vulnerable individuals the findings may be relevant for consideration for weight management, for those who may be at risk of becoming overweight or obese. In particular, findings that despite the differences in energy densities, appetite responses did not differ, nor was there complete energy compensation (15 % (ST) and 22 % (TM)) later during the day such that energy intakes were significantly lower on the days the standard energy meals were consumed compared to the energy dense meal.

This further supports lower energy intakes through reduced energy dense meals. It also seems that providing foods of altered form, results in reduced food and energy

intakes, although this is arguably because the meals were less palatable. Recommending the consumption of foods that are not palatable, whilst potentially reducing the quantity consumed, will likely have poor compliance to this dietary advice. The investigation would need to be repeated in obese individuals who are likely to adopt a weight management programme whereas this study used non obese individuals.

5.3 Future work

This study, including an extensive literature review across two complementary disciplines revealed a number of areas for future work. Not least to build the evidence base surrounding food based methods to manage those at risk of malnutrition, including those prescribed a TMD, in which the evidence continues to be lacking. These gaps in the evidence base for managing malnutrition likely contribute to the less than satisfactory improvement in the prevalence of malnutrition since it was re-identified as a problem over two decades ago (King's Fund 1992).

The results of this particular research evaluating the effect of enrichment as a strategy to improve energy intakes are promising, although a number of uncertainties remain. It has been proposed that the strategy evaluated in the current study; enrichment, may have particular relevance for those prescribed a TMD ("Texture E" or "Texture C"). However as previously outlined (section 5.2) these meals would need to be trialled in this group (*i.e.* group prescribed a TMD) in order to evaluate the application in this groups whilst also establishing appropriate enrichment levels.

It would however be unethical to trial this exact study design in a group with dysphagia due to use of different textures which may not be suitable depending on the severity of the swallowing disorder. It is proposed that a similar study take place using appropriate textures (depending on the individual's swallowing ability) which are enriched to different levels in order to identify suitable levels of enrichment for improving energy intakes in these individuals. Although acceptable thresholds for levels of enrichment are currently unknown, both the current study and previous studies (Odlund Olin et al. 1996; 2003) have demonstrated that enriching meals by 40-50% can result in increased energy intakes, and may therefore be a good starting point for developing enriched meals and setting targets for enrichment in practice.

Further, it would be useful to evaluate intakes over greater time periods (*i.e.* greater than 24 hours as per this current study) and to evaluate additional outcome measures including health outcomes, e.g. functional status, weight status and quality of life. It should be acknowledged however that even in a clinical setting, limitations surrounding the application to the clinical setting occur. In fact, as considered by Baldwin and Weekes (2012) the restrictive conditions imposed by clinical trials often do not mirror the more flexible conditions of clinical practice.

Using a similar design as in this study, it would also be useful to trial additional meals, in a healthy population in order to evaluate the benefit of providing a range of enriched meals to the diet which will also aid in meeting other nutrient requirements by providing a more varied diet. Investigating this would also allow the determination of the effect of enrichment at the different eating occasions and also provide more insight into the effect of enriching the total diet (perhaps to different levels) on appetite and intakes.

It would also be beneficial to develop enriched meals using different ingredients (other than saturated fat as per the current study) that may aid in secondary prevention which may be particularly relevant for application in a population with dysphagia, many of whom suffer with this condition as a result of a cerebrovascular incident (stroke) of which a diet high in saturated fat may be a contributing factor (Mensink et al. 2003; the Prospective Studies Collaboration, 2007). Although as previously discussed it is argued that addressing the issue of malnutrition may be prioritised; therefore an energy dense meal by any means (including fat), once it remains palatable, may act as an initial treatment option for those with reduced energy intakes. This may however not be appropriate for those requiring TMD long term.

It is recognised that provision of adequate nutrients is just one aspect of ensuring adequate intakes. Additional issues which may impact on achieving adequate food intakes in the clinical setting also need to be considered (chapter 1, sections 1.3.3 and chapter 5, section 5.2). This strategy of enrichment is however one which potentially could be used alongside other interventions. This is particularly true as it appears that the energy density can be altered substantially (40%) without impacting on detection, or compensation later in the day. Also with further supporting studies it could be argued that the provision of dietary advice surrounding enrichment tailored to the specific needs of the individual could be issued to allow self-management of the condition long term, even outside the hospital setting.

Overall there is considerable scope for additional research in order to manage those at risk of malnutrition, including those prescribed a TMD, using food based strategies. In those with poor swallow function, improving intakes via the oral route,

may have additional benefit in terms of improving swallow function. This is proposed since Robbins et al. (2007) demonstrated that after an eight week programme of exercises (isometric lingual exercise program by compressing an air-filled bulb between the tongue and the hard palate) lingual strength was improved in stroke patients with dysphagia. Further, they demonstrated that these same individuals developed greater lingual strength during swallowing naturally, as shown by higher swallowing pressures (Robbins et al. 2007). Perhaps the action of deglutition of foods itself would also contribute to increased lingual strength.

Although this particular study investigated improving energy intakes in adults, food based strategies offer advantages for children also. For example in children it has been found that limited exposure to solid food may disturb appetite regulation. In fact long term tube feeding can result in a loss of interest in food which is fundamental as motivation to eat is a survival instinct (Kane et al. 2011). The use of TMD for improving swallowing function and developing appetite regulation pathways however warrants further investigation.

Chapter 6: Conclusion

Despite the fact that malnutrition, referring to a state of undernutrition was first identified as a concern (particularly in hospitals) in 1992 (Kings Fund Centre Lennard-Jones 1992) and since then substantial efforts have been made to identify causes (chapter 1, section 1.1.2 Table 1.3) and put resolutions in place (chapter 1, section 1.2), it continues to be a problem. Unfortunately initiatives undertaken in an attempt to combat malnutrition which have included; collaboration with celebrity chefs and development of ample guidelines outlining voluntary practices (chapter 1, section 1.3.1, Table 1.7) have failed to meet their objectives. Whilst these strategies have had significant public support, media publicity and Governmental financial backing, it seems that these have been fundamentally based on an overall weak evidence base. In fact, a review conducted over five years ago identified a lack of studies investigating food based strategies to combat malnutrition (Weekes et al. 2009). Yet, still today this gap in the literature exists.

This current study which focused on the enrichment of meals suitable for provision in the clinical setting is one of many food based studies still needed to define the roles of food provision in overall nutritional care. A unique aspect of the current study was the investigation into the influence of texture modification and energy enrichment, which are advised despite the limited evidence base, on appetite and food intakes (g and kcal). For food based strategies to manage malnutrition to be effective, assessing their impact on eating behavior is fundamental to their longer

term success. However before now, no such studies exist which specifically examine the potential of such food based strategies on these outcomes, in a well-controlled design.

Prior to undertaking the current study it was hypothesised that altering a meal to represent one suitable for provision as part of a TMD would result in reduced food (g) and energy (kcal) intakes; however that subsequent enrichment of this TMD meal would result in increased energy intakes at a single eating occasion. It was unknown whether individuals would compensate by reducing energy intakes at eating occasions later in the day. On reflection of the key findings and supporting discussion, it is apparent that the data supports the study hypothesis that in fact enriching either a standard texture meal or a texture modified meal is effective for increasing energy intakes at a single meal occasion. No alterations in appetite responses (between meals), and also evidence of incomplete energy compensation later in the day resulted in significant increases in daily energy intakes, that may become clinically significant over time.

The current study demonstrated significant increases in daily energy intakes in healthy individuals, not confounded by disrupted appetite regulation through the addition of energy dense ingredients, in line with the ‘food first’ approach, which is advocated as a first approach for nutritional care in dietetic practice (NICE 2006; BDA 2012b,c). It was considered a particular strength of this current study that disease state was controlled for, which other studies (Odlund Olin et al 1996; Gall et al. 1998) have failed to do. In the current study enrichment was achieved through the addition of relatively cheap, familiar and widely available ingredients. Therefore public health advice which encompasses such enrichment techniques could be

developed allowing application in the community, where malnutrition is widely prevalent (BAPEN 2012a). This self-management technique also allows individuals to care for themselves at home without the need for specialist ingredients, equipment or substantial support.

As the test meals used in the current study were designed to specifically match guidance issued on the provision of hospital foods, the findings from this study could be incorporated into institutional food provision services. Although it is recognised that this would need to be further trialled in a clinical setting, considering the additional factors which can contribute to poor nutritional intakes as discussed within this thesis (chapter 1, sections 1.3.3 and 1.4.2).

It is hypothesised that those in the clinical setting may not achieve such improvements in energy intakes, due to disease state, and mastication ability which may lead to increased oral exposure times and consequently reduced food intakes due to early satiety from SSS. It is likely that to maximise intakes additional strategies such as assistance with eating, and improvements to food provision services, such as increased development of recipes in consultation with patient populations would be needed also. Texture modified meals were rated to be less palatable, which likely contributed to their reduced consumption. Therefore additional work into their development to ensure aesthetically pleasing products that are fit for purpose is warranted.

In summary, the results from this research it can be concluded that enriching a meal suitable for serving in the hospital setting results in significantly greater energy intakes (kcal) at an individual eating occasion for both ST and TM meals. No

observed differences in absolute food intakes or appetite responses between the meal conditions demonstrates the potential of enrichment as a strategy for improving energy intakes without impacting on appetite responses or food intakes (g). Little evidence of subsequent energy compensation resulted in daily energy intakes remaining significantly higher with consumption of the enriched meals. Evidence supporting enrichment of the total diet is however still needed. Further work, including studies of longer duration, into the development of suitable meals for those requiring a TMD, which maintain their palatability would be extremely useful in order to further improve food and energy in this potentially nutritionally vulnerable group. Greater meal choice is important for ensuring a balanced diet with adequate intakes of all nutrients, and reducing the impact of sensory fatigue/ SSS to certain meals.

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List of Appendices:

- Appendix 1: Full description of “Texture E” category requirements
- Appendix 2: Full list of ingredients (quantities and descriptions)
- Appendix 3: (a-d) Recipes, protocol and yields for each meal type
- Appendix 4: Recruitment flyer/moderator (for pilot)
- Appendix 5: Evaluation sheet for pilot study
- Appendix 6: TFEQ and marking system
- Appendix 7a: General recruitment flyer (all ages)
- Appendix 7b: Recruitment letter aimed at carers
- Appendix 8: Information sheet
- Appendix 9: Breakdown of requirements for participation
- Appendix 10: Diet diary
- Appendix 11: Consent form
- Appendix 12: Testing Workbook
- Appendix 13: Reiterating outline of session
- Appendix 14: Main results when adjusted with Bonferroni
- Appendix 15: Results from the assessment of the validity of the diet diary data
- Appendix 16: CONSORT checklist

Appendix 1:

Texture E category requirements

Table 3.2: Description for a “Texture E” “*fork mashable dysphagia*” diet

Texture E	<ul style="list-style-type: none">○ Food is soft, tender and moist but needs some chewing.○ It can be mashed with a fork.○ It usually requires a thick, smooth sauce, gravy or custard○ Any fluid, gravy, sauce or custard in or on the food is thick○ No mixed (thick-thin) textures. No thin loose fluid.○ No hard, tough, chewy, fibrous, stringy, dry, crispy, crunchy or crumbly bits.○ No pips, seeds, pith/inside skin. No skins or outer shells e.g. on peas, grapes. No husks.○ No skin, bone or gristle.○ No round or long-shaped foods e.g. sausages, grapes, sweets.○ No hard chunks e.g. pieces of apple.○ No sticky foods e.g. cheese chunks, marshmallows.○ No ‘floppy’ foods e.g. lettuce, cucumber, uncooked baby spinach leaves.○ No juicy food where juice separates off in the mouth to a mixed texture e.g. water melon.
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Source: BDA, 2012 (b). “National descriptors for texture modified foods and fluids.”

Appendix 2:

Ingredient information for standard and energy dense meals

Ingredient (Raw)	Quantity (g) *	
	<u>Standard</u>	<u>Energy dense</u>
Minced beef (lean) Morrison's, lean <12% fat	80	85
Carrots (diced) Morrison's loose carrots	70	70
Mushrooms (sliced and diced) Morrison's closed cup	30	25
Onion powder Morrison's onion granules	1	1
Vegetable oil Sunflower oil	0	5
Worcestershire sauce Morrison's own brand	6.5	6.5
Gravy granules Bisto beef gravy granules	4	4
Tomato puree Morrison's own brand	4	4
Chicken stock Knorr chicken stock cubes	64	64
Potatoes (peeled and halved/sliced) Rooster	160	160
Milk Morrison's semi skimmed	20	0
Spread (standard recipe) Flora 60% fat	5	0
Spread (energy dense recipe) <i>Clover 75% fat</i>	0	11
Cream (double) Morrison's fresh double cream	0	12

* Per 390g portion

Appendix 3 (a-d):

Recipes and protocol for all meals

(3a) STANDARD TEXTURE/STANDARD ENERGY (ST SE)

Ingredient	Quantity / portion	Quantity per test meal (3 portions)
Minced beef (lean)	80g	240g
Mushrooms	30g	90g
Carrots	70g	210g
Onion powder	1g	3g
Gravy granules	5g	15g
Worcester Sauce	6.5g	19.5g
Tomato Puree	4g	12g
Chicken Stock*	64 ml	190ml
Potatoes	150g	450g
Milk (semi skim)	20ml	60ml
Butter (60% fat, PUFA)	5g	15g

METHOD:

Prep:

- Weigh out onion powder, tomato puree, and Worcestershire sauce in separate dishes
- Peel and dice carrots and peel and half 225g of potatoes (ensuring similar sizes)
- Peel and slice the remaining 225g of potatoes
- Prepare chicken stock using “knorr” chicken stock cubes. To prepare stock, add 5 g of chicken stock cube to 450 ml boiling water and stir.

Method

- Add the mince beef (a little at a time) to a frying pan and cook until browned along with 5 ml of chicken stock (to avoid sticking to pan)
- Add the tomato puree, carrots, mushrooms and onion powder
- Add the Worcestershire sauce and chicken stock (185 ml) and cover
- Cover to minimise moisture losses and continue to cook on a low simmer for 25 minutes.
- Meanwhile, cover the (sliced and halved) potatoes in water and bring to the boil. Once boiling, reduce to a simmer and cook until tender (takes approx. 10-17 minutes). Sliced potatoes will cook faster than halved potatoes therefore cook in separate pot until slightly tender (not mushy) and drain.
- When cooked, drain remaining potatoes well and return to the pot and mash, adding milk/butter.

To serve:

- Add the meat mixture to the serving dish (718g meat mixture)
- Layer the sliced potatoes on top of the meat
- and then cover with mash potato
- Cover with tinfoil
- Bake in a preheated oven (180°C) for a further 40 minutes

(3b) STANDARD TEXTURE/ ENERGY DENSE (ST ED)

Ingredient	Quantity / portion	Quantity per test meal (3 portions)
Minced beef (lean)	85g	255g
Sunflower oil	6g	18g
Mushrooms	25g	75g
Carrots	70g	210g
Onion powder	1g	3g
Worcester Sauce	6.5g	19.5g
Gravy Granules	5	15g
Tomato Puree	4g	12g
Chicken Stock	64ml	190g
Potatoes	150g	450g
Double cream	11g	33g
Butter (70% fat, PUFA)	12g	36g

METHOD:*Prep:*

- Weigh out onion powder, tomato puree, and Worcestershire sauce in separate dishes
- Peel and dice carrots, and peel and half 225g of potatoes (ensuring similar sizes) (image 2)
- Peel and slice the remaining 225g of potatoes
- Prepare chicken stock using “knorr” chicken stock cubes. To prepare stock, add 5 g of chicken stock cube to 450 ml boiling water and stir.

Method

- Add the mince beef (a little at a time) to a frying pan and cook until browned along with 5 ml of chicken stock (to avoid sticking to pan)
- Add the tomato puree, carrots, mushrooms and onion powder
- Add the Worcestershire sauce and chicken stock (185 ml) and cover
- Cover and continue to cook on a low simmer for 25 minutes.
- Meanwhile, cover the (sliced and halved) potatoes in water and bring to the boil. Once boiling, reduce to a simmer and cook until tender (takes approx. 10-17 minutes). Sliced potatoes will cook faster than halved potatoes therefore cook in separate pot until slightly tender (not mushy) and drain.
- When cooked, drain remaining potatoes well and return to the pot and mash, adding cream/butter.

To serve:

- Add the meat mixture to the serving dish
- Layer the sliced potatoes on top of the meat
- and cover with mash potato
- Cover with tinfoil
- Bake in a preheated oven (180°C) for a further 40 minutes

(3c) TEXTURE MODIFIED/ STANDARD ENERGY (TM SE)

Ingredient	Quantity / portion	Quantity per test meal (3 portions)
Minced beef (lean)	104g	312g
Mushrooms	39g	117g
Carrots	91g	273g
Onion powder	1g	3g
Worcester Sauce	8.45g	25g
Tomato Puree	5.2g	16g
Gravy granules	5g	15g
Chicken Stock	64ml	190ml
Potatoes	150g	450g
Milk (semi skim)	20ml	60ml
Butter (60% fat, PUFA)	5g	15g

The quantities used for the texture modified versions have been scaled up by 30% in order to account for losses during texture preparation and to ensure that the quantity of product yielded matches that of its standard texture counterpart. Scaling was calculated based on an average loss of ~26%. It was decided then to round up to 30%.

METHOD*Prep:*

- Weigh out onion powder, tomato puree, and Worcestershire sauce in separate dishes
- Peel and dice carrots, and peel and half potatoes (ensuring similar sizes)
- Prepare chicken stock using “knorr” chicken stock cubes. To prepare stock, add 5 g of chicken stock cube to 450 ml boiling water and stir.

Method

- Add the mince beef (a little at a time) to a frying pan and cook until browned along with 5 ml of chicken stock (to avoid sticking to pan)
- Add the tomato puree, carrots, mushrooms and onion powder.
- Add the Worcestershire sauce and chicken stock (185 ml) and cover
- Cover and continue to cook on a low simmer for 25 minutes.
- Meanwhile, cover potatoes in water and bring to the boil. Once boiling, reduce to a simmer and cook until tender (takes approx. 12-17 minutes). Drain well and return to the pot and mash, adding milk/butter.

Texture preparation:

- In a bowl, using a handheld blender- blend the carrot and beef mixture, adding remaining chicken stock (NB add liquid in small quantities as required in order to achieve optimum texture) until it represents a smooth consistent texture (Image 6). Using the metal sieve (image 7), pass the mixture through the sieve

To serve:

- Add the meat mixture to the serving dish and cover with the mash potato.
- Cover with tin foil and bake in a preheated oven (180 °C) for 40 minutes

(3d) TEXTURE MODIFIED/ ENERGY DENSE (TM ED)

Ingredient	Quantity / portion	Quantity per test meal (3 portions)
Sunflower oil	6g	18g
Minced beef (lean)	110g	330g
Mushrooms	32.5g	97.5g
Carrots	91g	273g
Onion powder	1g	3g
Worcester Sauce	8.45g	25g
Tomato Puree	5.2g	16g
Gray granule	5g	15g
Chicken Stock	64ml	190ml
Potatoes	150g	450g
Double cream	11ml	33ml
Butter (75% fat, PUFA)	12g	36g

METHOD*Prep:*

- Weigh out onion powder, tomato puree, and Worcestershire sauce in separate dishes
- Peel and dice carrots, and peel and half potatoes (ensuring similar sizes)
- Prepare chicken stock using “knorr” chicken stock cubes. To prepare stock, add 5 g of chicken stock cube to 450 ml boiling water and stir.

Method (per individual portion)

- Add the mince beef (a little at a time) to a frying pan and cook until browned along with 5 ml of chicken stock (to avoid sticking to pan)
- Add the tomato puree, carrots, mushrooms and onion powder
- Add the Worcestershire sauce and chicken stock (185 ml) and cover
- Cover and continue to cook on a low simmer for 25 minutes.
- Meanwhile, cover potatoes in water and bring to the boil. Once boiling, reduce to a simmer and cook until tender (takes approx. 12-17 minutes). Drain well and return to the pot and mash, adding cream and butter.

Texture preparation:

- In a bowl, using a handheld blender- blend the carrot and beef mixture, adding remaining chicken stock NB add liquid in small quantities as required in order to achieve optimum texture) until it represents a smooth consistent texture (Image 6). Using the metal sieve (image 7), pass the mixture through the sieve

To serve:

- Add the meat mixture to the serving dish and cover with the mash potato.
- Cover with tin foil and bake in a preheated oven (180 °C) for 40 minute

Appendix 4: Recruitment for pilot



Queen Margaret University
EDINBURGH

Would you like to take part in valuable research while receiving a free lunch??



Participation requires attending 1 lunchtime tasting session (lasting no longer than 90 minutes) where you will be asked to consume a beef based cottage pie until you are comfortably full. As well as tasting the test meal, you will be required to answer a series of questions that ask you to rate the food you have eaten for different parameters, and to complete an evaluation sheet. The findings of the research will contribute to a larger study which aims to inform food service provision for nutritionally vulnerable individuals in the hospital and care home settings.

Recruitment is open to men and women aged 50 years or more. Regrettably, those receiving a therapeutic diet or with allergies to any of the ingredients (listed overleaf) cannot participate in the study.

If interested or would like to find out more please contact me by email or phone at:

SPritchard@qmu.ac.uk/ 0131 474 0000 (and ask to speak to Sarah Pritchard)

This project has ethical approval.

Thank You

Please read the following list of ingredients used in test meal which may affect your participation:

Beef Onion powder Tomato puree Potato Butter Cow's Milk Cream Chicken stock Mushrooms
Carrots Vegetable oil Worcestershire sauce

Appendix 5: Evaluation sheet for pilot study



Queen Margaret University
EDINBURGH

Evaluation Sheet

1) Session timings

Do you feel the session ran for the appropriate length of time?

2) Workbook

Was the workbook comprehensible?

Is there anything about the workbook that you would change in order to increase the ease of its completion?

Was there sufficient time to answer all of the questions?

3) Other

Any additional comments?

Appendix 6:**Three Factor Eating Questionnaire (TFEQ)****Participant Number**_____**Part 1**

Please circle the answer which in your experience, most closely relates to the question asked.

T=True, F=False

1. When I have eaten my quota of calories , I am usually good about not eating any more	T	F
2. I deliberately take small helpings as a mean of controlling my weight	T	F
3. Life is too short to worry about dieting	T	F
4. I have a pretty good idea of the number of calories in common foods	T	F
5. While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it	T	F
6. I enjoy eating too much to spoil it by counting calories or watching my weight	T	F
7. I often stop eating when i am not really full as a conscious means of limiting the amount that I eat	T	F
8. I consciously hold back at meals in order not to gain weight	T	F
9. I eat anything I want, any time I want	T	F
10. I count calories as a conscious means of controlling my weight	T	F
11. I do not eat some foods because they make me fat	T	F
12. I pay a great deal of attention to changes to my figure	T	F

Part 2

Please circle the answer which in your experience, most closely relates to the question asked.

1. How often are you dieting in a conscious effort to control your weight?

Rarely Sometimes Usually Always

2. Would a weight fluctuation of 5 lbs. affect the way you live your life?

Not at all Slightly Moderately Very much

3. Do your feelings of guilt about overeating help you to control your food intake?

Never Rarely Often Always

4. How conscious are you of what you are eating?

Not at all Slightly Moderately Extremely

5. How frequently do you avoid “stocking up” on tempting foods?

Almost never Seldom Usually Almost always

6. How likely are you to shop for low calorie foods?

Unlikely Slightly likely Moderately likely Very Likely

7. How likely are you to consciously eat slowly in order to cut down on how much you eat?

Unlikely Slightly likely Moderately likely Very Likely

8. How likely are you to consciously eat less than you want?

Unlikely Slightly likely Moderately likely Very Likely

9. On a scale of 0-5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in") what number would you give yourself?

0= eat whatever you want, when you want it

1= usually eat whatever you want, whenever you want it

2= often eat whatever you want, whenever you want it

3= often limit food intake, but often "give in"

4= usually limit food intake, rarely "give in"

5= constantly limiting food intake, never "giving in"

Three Factor Eating Questionnaire RESULTS- BOLD answers receive 1 point

Part 1

Please circle the answer which in your experience, most closely relates to the question asked.

T=True, F=False

13. When I have eaten my quota of calories , I am usually good about not eating any more	T	F
14. I deliberately take small helpings as a mean of controlling my weight	T	F
15. Life is too short to worry about dieting	T	F
16. I have a pretty good idea of the number of calories in common foods	T	F
17. While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it	T	F
18. I enjoy eating too much to spoil it by counting calories or watching my weight	T	F
19. I often stop eating when i am not really full as a conscious means of limiting the amount that I eat	T	F
20. I consciously hold back at meals in order not to gain weight	T	F
21. I eat anything I want, any time I want	T	F
22. I count calories as a conscious means of controlling my weight	T	F
23. I do not eat some foods because they make me fat	T	F
24. I pay a great deal of attention to changes to my figure	T	F

Part 2

Please circle the answer which in your experience, most closely relates to the question asked.

10. How often are you dieting in a conscious effort to control your weight?

Rarely Sometimes **Usually** **Always**

11. Would a weight fluctuation of 5 lbs. affect the way you live your life?

Not at all Slightly **Moderately** **Very much**

12. Do your feelings of guilt about overeating help you to control your food intake?

Never Rarely **Often** **Always**

13. How conscious are you of what you are eating?

Not at all Slightly **Moderately** **Extremely**

14. How frequently do you avoid “stocking up” on tempting foods?

Almost never

Seldom

Usually

Almost always

15. How likely are you to shop for low calorie foods?

Unlikely

Slightly likely

Moderately likely

Very Likely

16. How likely are you to consciously eat slowly in order to cut down on how much you eat?

Unlikely

Slightly likely

Moderately likely

Very Likely

17. How likely are you to consciously eat less than you want?

Unlikely

Slightly likely

Moderately likely

Very Likely

18. On a scale of 0-5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never “giving in”) what number would you give yourself?

0= eat whatever you want, when you want it

1= usually eat whatever you want, whenever you want it

2= often eat whatever you want, whenever you want it

3= often limit food intake, but often “give in”

4= usually limit food intake, rarely “give in”

5= constantly limiting food intake, never “giving in”



Appendix 7a: General recruitment flyer



Queen Margaret University
EDINBURGH

Would you like to take part in valuable research while receiving a free lunch??



Participation involves a series of lunchtime tasting sessions (each lasting no longer than 60 minutes) at **Queen Margaret University's Feeding Centre, Musselburgh**. There are **4 test days** which will be arranged at your convenience over a period of 6 months. As well as consuming the meal, you will be required to complete a short questionnaire that asks you to rate the food you have eaten for different parameters. You will also be asked to keep a food record for each of the test days. The meal to be served on the testing days is a beef based cottage pie.

Participation is open to men and women aged at least 18 years. Regrettably, those who are dieting or receiving a therapeutic diet, have dentures, suffer from any metabolic disorders (such as diabetes), have a BMI >30, have allergies to any of the test ingredients (*listed below), or are taking medication that may affect appetite, cannot participate in this study.

The findings of this research will provide useful information to inform food service provision for potential nutritionally vulnerable individuals in the hospital and care home settings.

If interested, or would like to find out more please contact me by phone or email at:

SPritchard@qmu.ac.uk

Or @ 0131 474 0000 (and ask to speak to Sarah Pritchard)

*Please read the following list of ingredients used in the test meal which may affect your participation:
Beef, Onion powder, Tomato puree, Potato, Butter, Cow's milk, Chicken stock, Gravy granules, Mushrooms, Carrots, Vegetable oil, Worcestershire sauce, Cream

Thank You

Appendix 7b:

Recruitment flyer aimed at carers

Would you like to take part in valuable research while receiving a free lunch??

- Are you at least 50 years of age?
- Are you caring for someone who has difficulty eating and meeting their food requirements?
- **Would you like to take part in valuable research which aims to maximise the opportunity for people to meet their food intake requirements?**

Participation involves a series of lunchtime tasting sessions (each lasting no longer than 60 minutes) at **Queen Margaret University's Feeding Centre, Musselburgh**. There are 4 test days which will be arranged at your convenience over a period of 6 months. As well as tasting the test meal, you will be required to complete a short workbook that asks you to rate the food you have eaten for different parameters. You will also be asked to keep a food record for each of the test days. The meal to be served on the testing days is a beef based cottage pie.

The findings of this research will provide useful information to inform food service provision for nutritionally vulnerable individuals in the hospital and care home settings.

If interested, or would like to find out more please contact me by phone or email at:
SPritchard @qmu.ac.uk or 0131 474 0000 (and ask to speak to Sarah Pritchard)

Or complete the **reply slip** below and send to QMU using the prepaid envelope attached

I am interested in this research and would like to be contacted about taking part/hearing more about it.

Name: _____

Contact Number: _____

Mobile: _____

Email: _____

Address: _____

Appendix 8: Information sheet



Queen Margaret University
EDINBURGH

My name is Sarah Pritchard and I am a Public Health Nutritionist currently undertaking a PhD at the School of Health Sciences at Queen Margaret University in Edinburgh. My research is titled;

“The effect of different meal attributes on food intakes in adults”

This research is investigating different recipes and production techniques on food intakes. It is hoped that results from this study will inform the development of recipes to improve food intakes in adults and older adults in hospitals and care homes, which is vital to recovery, maintaining health and quality of life.

I am looking for volunteers to participate in the project. For this research I am recruiting men and women aged 18 years or more. Everybody who fits these criteria are invited to take part in the study. Regrettably, those who are allergic or intolerant to any of the meal ingredients (listed overleaf), are suffering from any medical condition or taking medication that may affect appetite, suffer with any metabolic disorders such as diabetes, have dentures, unable to give informed consent, have a BMI>30, are unable to travel to QMU, or currently dieting, cannot participate in this study.

If you agree to participate in the study, you will be asked to attend **1 consultation session** and **4 lunch sessions** held in Queen Margaret University (12.30 pm-1.30 pm). At the feeding session you will be provided with a serving of cottage pie (ingredients overleaf) which you will be asked to consume at your leisure until you are comfortably full. You will also be asked to answer a questionnaire relating to the meal that you have just consumed and how you feel. You will need to complete a food record listing all food and drink consumed in the morning prior to the feeding session and then for the remainder of that day.

All data that is collected will be anonymised so that nobody will know your results. Your name will be replaced with a participant number, and it will not be possible for you to be

identified in any reporting of the data gathered. Data will be stored in a password protected domain for a period of five years.

The results may be published in a journal or presented at a conference.

If you would like to contact an independent person, who knows about this project but is not involved in it, you are welcome to contact Sara Smith. Her contact details are given below.

Please read the following list of ingredients used in test meal which may affect your participation:

- Beef (lean)
- Butter
- Chicken stock
- Onion powder
- Cow's milk
- Mushrooms
- Tomato Puree
- Cream
- Carrots
- Gravy granules
- Worcestershire sauce
- Cream

Contact details of the lead researcher

Name of researcher: Sarah Pritchard (ANutr)

Address: Dietetics, Nutrition and Biological Sciences,
School of Health Sciences,
Queen Margaret University,
Musselburgh,
East Lothian
EH21 6UU

Email / Telephone: SPritchard@qmu.ac.uk / 0131 474 0000

Contact details of the independent adviser (not directly involved in this research)

Name of adviser: Dr. Sara Smith (RD)

Address: Dietetics, Nutrition and Biological Sciences,
School of Health Sciences,
Queen Margaret University,
Musselburgh,
East Lothian
EH21 6UU

Email / Telephone: SSmith@qmu.ac.uk / 0131 474 0000

Appendix 9:



Queen Margaret University
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MEAL ATTRIBUTES AND FOOD INTAKES

Thank you again for participating in this research, it is hoped that the findings from this study will inform the development of recipes to improve food intakes in adults in hospitals and care homes, which is vital to recovery, maintaining health and quality of life. The following document provides a summary of what is required of you in order to fulfil the participation criteria.

On the day before the test day:

- Avoid strenuous exercise
- Avoid alcohol consumption

On the test day:

- Eat your regular breakfast (at least 4 hours before arriving at QMU Feeding Centre at 12.25pm) NOTE: It is essential that you will consume the same breakfast on each of your test days.
- Record your dietary intake in the food diary provided including the TIME of consumption.
- Fast from breakfast until the test session (including coffee and tea)
- Avoid alcohol
- Avoid strenuous exercise

One hour prior to the session:

- Avoid smoking
- Avoid Caffeine

At the session:

- Familiarise yourself with the questionnaire
- Consume the meal until you feel comfortable full while completing the questionnaire
- Avoid contact with any other participants in the room

For the remainder of the day:

- Continue the day as you would normally
- Keep your **diet diary** for the remainder of the day (including **TIME** of consumption)
- Avoid alcohol
- Avoid strenuous exercise

Note: It is extremely important to keep each of your test days as standard as possible, for example by eating the same breakfast, avoiding alcohol and strenuous exercise.

It is also pertinent to the results of the study that all food consumed (over the entire test day) is recorded in the diet diary, accurately and also that the time of consumption is recorded.

If you have any questions relating to these instructions-please contact the researcher

Contact details of the researcher

Name of researcher: Sarah Pritchard

Address: Dietetics, Nutrition and Biological Science
School of Health Sciences,
Queen Margaret University,
Musselburgh
East Lothian EH21 6UU

Email / Telephone: SPritchard@qmu.ac.uk / 0131 474 000

Appendix 10: Food diary



Queen Margaret University
EDINBURGH

Participant number _____

This booklet contains 4 diet diary sheets. One sheet is to be filled in per test day and then returned to the researcher on the next day of testing. Please read the instructions below regarding the completion of the diet diaries. If you have any questions during completion of the diary, please contact the researcher; Sarah Pritchard on 0131 474 0000 or SPritchard@qmu.ac.uk

Guidelines for describing food and drink

Please write down what you eat and drink giving as much detail as possible about each item.

- | | |
|-----------------|---|
| Cooking methods | - Give the method of cooking. <ul style="list-style-type: none">- Are your eggs boiled, poached or scrambled?- Are your potatoes boiled, mashed, fried or chipped?- Is your bacon grilled or fried? |
| Brand names | - Write down the brand names of foods and drinks where you can, e.g. Flora margarine, Jacob's crackers. |
| Names of foods | - Name the type of biscuit, cake or cereal you eat, e.g. digestive biscuit, fruit cake, Weetabix. Name the type of milk, e.g. skimmed, semi-skimmed, full fat. |
| Homemade meals | - Write down what the dish is called and give the ingredients if you can, e.g. spaghetti bolognese (minced beef, tinned tomatoes, carrots, celery etc.) or cheese sandwich (cheddar cheese, brown bread, butter). |

Food diaries aim to measure food intake as accurately as possible therefore it is ideal to weigh and record each food and drink item consumed. This however can be impractical to implement in a real life setting. It is therefore recommended that the following tips are used to accurately estimate the quantities of foods we are consuming.

Tips for estimating weights:

1. Use weights recorded on wrappers/ packaging of bought foods, for example - crisps, chocolate, sweets, cans of drink, etc.
2. Use numbers and size of separate pieces, for example – 2 plums, 6 small new potatoes, ¼ honeydew melon, etc.
3. Use household measures, for example - 1 teaspoon, 2 dessertspoons, 1 tablespoon, 1 cup, 1 mug etc.

Time of consumption:

It is crucial to this research that the time that each food and drink that is consumed is recorded. There is a column on the left hand side of the page to record this (example on the next page).

Food diary example

Day Wednesday Date 1st June 2011

*Start a separate sheet for each day.
Leave a line for each snack or meal.*

<i>Time</i>	<i>Details of food and drink</i>	<i>Amount/ weight</i>
8.00am	Tea	200ml
	semi skimmed milk	20ml
	Sugar	2 teaspoons
	Mother's Pride white bread, toasted	2 slices
	Butter (Flora buttery)	Thin spread
	Jam (raspberry)	2 teaspoons
11.00am	Cappuccino (Costa coffee)	1 medium cup
	Dark chocolate digestive biscuits	2 biscuits
	Mars Bar	62.5g (as per packet)
12:15pm	White baguette	40g
	Cheddar cheese	35g
	Tomato	1 medium
	Banana	1 large
	Walkers salt and vinegar crisps	34.5g (as per packet)
	Apple	1 small
	Orange juice with bits	200g
3:00pm	Coffee black	1 cup (standard)
	Chocolate fudge cake	150g
7:00pm	Grilled pork chop	180g
	Thick gravy	2 tablespoons
	Mashed potato	2 small potatoes
	Butter (Flora buttery)	1 teaspoon
	Peas (frozen)	40g
	Vanilla ice cream	3 scoops
9:30pm	Tea	1 cup (standard)
	semi-skimmed milk	20ml
	Sugar	2 teaspoons
	Dark chocolate digestive biscuits	2 biscuits

Appendix 11: Consent form



Queen Margaret University

EDINBURGH

“Meal attributes and food intakes”.

I have read and understood the information sheet and this consent form.

I have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study.

I understand that I have the right to withdraw from this study at any stage without giving any reason.

I agree to participate in this study.

Name of participant: _____

Contact details of participant:

Address: _____

Phone number(s): _____

Email: _____

Preferred method of contact (circle): Post / Phone / Email / Any

Signature of participant: _____

Signature of researcher: _____

Date: _____

Appendix 12: Workbook



Queen Margaret University
EDINBURGH

Participant Number:

Meal Code:

Testing Session Workbook

The next few pages consist of a series of scales that ask you to indicate your rating of the meal and how you feel after it. Please read each question carefully and indicate your rating for each item.

You will be required to consume your meal as you fill out the workbook. You will need to consume the meal until you reach a point where you are comfortably full (satiation). When you reach this point, please alert the researcher. You must however proceed to answer all the questions in the workbook, even after you have reached satiation. Questions will be asked at specific times (on the sounding of an alarm) so please take time reading each question.

You may refill your plate at any time throughout the study.

If you are ready to start, please answer question 1 (Q1) before you serve your meal

This is to be answered **before** food is served

Q.1 VAS 1

Q 1.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____

Q 1.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____

Q 1.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____

Please now **serve yourself** a portion of the test meal. **Do not taste** the food.

Q.2 VAS 2

Q 2.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q.2.2 Please indicate using the scale below, rate your level of **FULLNESS**

Not at all _____ Extremely

Q 2.3 Please indicate using the scale below, rate your **DESIRE TO EAT**
None at all _____ Extreme

Please take **one bite/mouthful** of the meal and answer the following questions.

Q. 3 VAS 3

Q 3.1 Please indicate using the scale below, how **HUNGRY** you feel
Not at all _____ Extremely

Q 3.2 Please indicate using the scale below, your level of **FULLNESS**
Not at all _____ Extremely

Q 3.3 Please indicate using the scale below, how **PALATABLE** you rate the food to be
Not at all _____ Extremely

Q 3.4 Please indicate using the scale below, your **DESIRE TO EAT**
None at all _____ Extreme

Now, please **consume the food** as you would normally. Subsequent questions are to be answered at **ten minute** intervals. You will be alerted to these times by a familiar alarm.

If you reach a point where you are comfortably full (satiation) before the alarm rings, please alert the researcher.

NB: You must however continue to answer the questions on the sounding of the alarm.

I have read these instructions (tick as appropriate).

☐

To be answered on sounding of **first alarm**

Q. 4 VAS 4

Q 4.1 Please indicate using the scale below, how **HUNGRY** you feel
Not at all _____ Extremely

Q 4.2 Please indicate using the scale below, level of **FULLNESS**

Not at all _____ Extremely

Q 4.3 Please indicate using the scale below, **DESIRE TO EAT**

None at all _____ Extreme

Q 4.4 Please indicate using the scale below, how **PALATABLE** you rate the food to be

Not at all _____ Extremely

Q 4.5 Have you reached satiation? (*Tick as appropriate*)

Yes

No

If you answered “**Yes**”, and have not done so already please alert the researcher.

NB: You must however continue to answer the remaining questions on the sounding of the alarms.

If you answered “**No**”, please continue consuming until you reach satiation.

If you reach satiation before the next alarm rings, please alert the researcher.

To be answered on sounding of **second alarm**

Q. 5 VAS 5

Q 5.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q 5.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____ Extremely

Q 5.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____ Extreme

Q. 5.4 Please indicate using the scale below, how **PALATABLE** you rate the food to be

Not at all _____ Extremely

Q. 5.5 Have you reached satiation? (*Tick as appropriate*)

Yes

No

If you answered “**Yes**” and have not done so already please alert the researcher.

NB: You must however continue to answer the remaining questions on the sounding of the alarm.

If you answered “**No**”, please continue consuming until you reach satiation

If you reach satiation before the next alarm rings, alert the researcher.

To be answered on sounding of **third alarm**

Q. 6 VAS 6

Q 6.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q 6.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____ Extremely

Q 6.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____ Extreme

Q 6.4 Please indicate using the scale below, how **PALATABLE** you rate the food

Not at all _____ Extremely

Q 6.5 Have you reached satiation? (*Tick as appropriate*)

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

If you answered “**Yes**” and have not done so already please alert the researcher.

NB: You must however continue to answer the remaining questions on the sounding of the alarms.

If you answered “**No**”, please continue consuming until you reach satiation

If you reach satiation before the next alarm rings, alert the researcher.

To be answered on sounding of **fourth alarm**

Q. 7 VAS 7

Q 7.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q 7.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____

Q 7.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____ Extreme

Q 7.4 Please indicate using the scale below, how **PALATABLE** you rate the food to be

Not at all _____ Extremely

Q 7.5 Have you reached satiation? (*Tick as appropriate*)

Yes

☐

No

☐

If you answered “**Yes**” and have not done so already please alert the researcher.

NB: You must however continue to answer the remaining questions on the sounding of the alarms.

If you answered “**No**”, please continue consuming until you reach satiation

If you reach satiation before the next alarm rings, alert the researcher.

To be answered on sounding of **fifth alarm**

Q. 8 VAS 8

Q 8.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q 8.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____ Extremely

Q 8.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____ Extreme

Q 8.4 Please indicate using the scale below, how **PALATABLE** you rate the food to be

Not at all _____ Extremely

Q 8.5 Have you reached satiation? (*Tick as appropriate*)

Yes

☐

No

☐

If you answered “**Yes**” and have not done so already please alert the researcher.

NB: You must however continue to answer the remaining questions on the sounding of the alarms.

If you answered “**No**”, please continue consuming until you reach satiation

If you reach satiation before the next alarm rings, please alert the researcher.

To be answered on sounding of **sixth alarm**

Q.9 VAS 9

Q 9.1 Please indicate using the scale below, how **HUNGRY** you feel

Not at all _____ Extremely

Q 9.2 Please indicate using the scale below, your level of **FULLNESS**

Not at all _____ Extremely

Q 9.3 Please indicate using the scale below, your **DESIRE TO EAT**

None at all _____ Extreme

Q 9.4 Please indicate using the scale below, how **PALATABLE** you rate the food to be

Not at all _____ Extremely

Q 9.5 Have you reached satiation? (*Tick as appropriate*)

Yes
No

<input type="checkbox"/>
<input type="checkbox"/>

This session is now over, thank you again for your time. Please ensure you return your worksheet to the researcher before you leave the centre. Thank you.

Appendix 13: Overview of testing session



Queen Margaret University
EDINBURGH

∞ Thank you again for participating in this research, your time and interest is greatly appreciated ∞

Instructions to participants:

This session will involve the **consumption** a food product and is expected to last no longer than 90 minutes. At the session you will be presented with a workbook which includes a number of rating scales to be filled out at indicated times. You will be asked to serve yourself some cottage pie to eat until you reach a point where you no longer feel like consuming anymore. **You can refill your plate freely throughout the session.**

Before and throughout the session you will be required to rate the meal and also how you feel after eating the meal, on a scale indicating your level of fullness and desire to eat. You will need to complete these scales at a number of directed time points, *i.e.*

- When you enter the room, before the food has been served,
- before your first bite,
- after your first bite,
- **every ten minutes** for the following hour (you will be alerted by a familiar alarm when this time has elapsed).

Any questions before testing begins?

Appendix 14: Post hoc tests adjusted with Bonferroni

Food Intake (g) at session

When adjusted with Bonferroni-Post hoc tests did not detect where significant differences lay however food intake of the ST SE meal was higher than both the TM SE and TM ED meals ($p=0.084$ and $p=0.06$ respectively).

Energy intakes (kcal) at session

Adjusted with Bonferroni: Post hoc analysis revealed that energy intakes were significantly higher with energy enrichment of both a ST ($p=0.001$) and TM meal ($p=0.001$). Energy intakes were also higher with consumption of the TM ED meal compared to ST SE meal ($p=0.001$). Whilst energy intakes did appear to be reduced with texture modification, this finding was not significant. Energy intakes were significantly higher with ST ED than with TM SE ($p=0.001$).

Daily energy intakes (kcal)

Post hoc analysis corrected with Bonferroni revealed that daily energy intake was significantly greater when the ED meals were consumed at lunch for both ST ($p=0.006$) and TM meals ($p=0.04$).

Contribution of test meal to total daily energy

Post hoc analysis revealed that the ST SE meal contributed significantly less energy to total daily energy intake compared to the ED meals for both ST ($p=0.001$) and TM ($p=0.005$) meals, and that the TM SE meal contributed significantly less energy to total daily energy intake compared to the ST ED meal ($p=0.001$).

Appendix 15: Differences in daily energy intakes relative to estimated requirements for each participant

BMR x PAL	Diff 741	Diff 682	Diff 423	Diff 314
2832	-891	-821	-352	-460
2804	524	935	90	232
1896	-266	-389	-305	-771
2269	-1132	-520	-1171	-770
3141	-229	-299	-803	-326
2454	-1237	-775	-864	-948
2254	-1096	111	-658	-471
3251	-1447	-655	-1342	-438
2076	-227	-275	-477	5
2128	-664	-332	-467	-328
2311	-427	-121	-306	481
1999	-168	-118	-360	-230
2415	-377	768	-67	749
2091	340	121	-303	-73
2189	-793	-792	211	-174
2473	68	-316	-29	257
2029	-460	259	-152	-181
2331	-45	495	83	694
1889	-265	-182	-83	796
2055	461	1027	131	487
2372	-482	-152	-262	-361
1840	-611	-426	-794	-474
2137	-273	19	-375	-398
2281	-286	-525	391	-358
2496	-542	-313	-1200	-588
2308	-188	-542	-1209	-529
2883	-626	-163	-586	-130
2175	-248	169	-430	60
2178	-340	71	128	25
1812	-555	-350	-461	-252
2138	-511	-740	-876	-819
2117	-85	350	194	-85
2211	-466	-455	-812	-725

Appendix 16: CONSORT checklist.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Cover
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	IXV
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	8-115
	2b	Specific objectives or hypotheses	115-117
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	180
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	189
Participants	4a	Eligibility criteria for participants	181
	4b	Settings and locations where the data were collected	182-199
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	182-199
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	201-210
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	182-184
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			181
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	181
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	

mechanism			181
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	180
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	180
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	210-214
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	191+215
	13b	For each group, losses and exclusions after randomisation, together with reasons	191 +215
Recruitment	14a	Dates defining the periods of recruitment and follow-up	216
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	216
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	215-239
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	240-303
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	273-294
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	240-269

Other information

Registration	23	Registration number and name of trial registry	N/A
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.